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Medico-Legal Aspects of Telemedicine Practice
with Special Reference to Cross-Border
Telemedicine Practice between
Hong Kong and Mainland China
實踐「遠端醫療」的醫療法律責任：
特別論及香港和中國內地之間的
跨境「遠端醫療」實務

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ABSTRACT

Telemedicine has changed the methods of communications between health practitioners and patients by breaking both territorial frontiers and boundaries between different health professionals. It has also enhanced people's access to health care for previously not-easily-accessible populations and improved quality of health service, as well as strengthened discourse between patients and health practitioners. However, the development of telemedicine is impeded by legal uncertainty, *inter alia*, as not every society pays sufficient legal attention to this technological advancement. Hong Kong and China are no exception.

It is anticipated that the demand for cross-border clinical exchange and services between Hong Kong and China will grow. To facilitate a sustainable medical development, it is important to have a proper understanding on the law and regulations in the respective jurisdictions, especially the potential medico-legal liability of health practitioners and health institutes as well as the rights of patients before telemedical services rocket across the two territories.

This thesis conducts a critical review to the potential medico-legal liability of cross-border telemedicine between Hong Kong and China with reference to international treaties, national/domestic laws, rules and regulations, professional guidelines and practical experiences in different countries, aiming at offering a legal reference to health practitioners and institutes providing the state-of-the-art services and to patients who receive online health services across the two territories. A further hope of this study is to at least arouse the interests of certain stakeholders with authority in checking the need for cross-border telemedicine, not for today but for tomorrow, and examining the current readiness including the legal aspects to support the sustainable growth of telemedicine in Hong Kong, China and across the two territories.

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Notice of the Supreme People’s Court on Trying Civil Cases on Medical Disputes by Referring to the ‘Regulation on Handling Medical Malpractices (*sic*)’ (6 January 2003) (最高人民法院關於參照‘醫療事故處理條例’審理醫療糾紛

民事案件的通知（2003 年 1 月 6 日）；*zuì gāo rén mín fǎ yuàn guān yú cān zhào ‘yī liáo shì gù chǔ lǐ tiáo lì’ shēn lǐ yī liáo jiū fēn mín shì àn jiàn de tōng zhī*（2003 nián 1 yuè 6 rì））

Opinions of the Supreme People’s Court on Several Issues concerning the Implementation of the General Principles on Civil Law（最高人民法院關於貫徹執行中華人民共和國民法通則若干問題的意見；*zuì gāo rén mín fǎ yuàn guān yú guān ché zhí xíng zhōng huá rén mín gòng hé guó mín fǎ tōng zé ruò gān wèn tí de yì jiàn*）1988

Regulation on the Handling of Medical Accidents of People’s Republic of China（中華人民共和國醫療事故處理條例；*zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*）2002

Tort Law of the People’s Republic of China（中華人民共和國侵權責任法；*zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ*）2010

Europe

Council of Europe, ‘European Social Charter’ (Turin, 18.X.1961)

—— ‘The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine’ (Oviedo, 4.IV.1997)

Council Directive 81/1057/EEC of 14 December 1981 supplementing Directives 75/362/EEC, 77/452/EEC, 78/686/EEC and 78/1026/EEC concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of doctors, nurses responsible for general care, dental practitioners and veterinary surgeons respectively, with regard to acquired rights
Council Directive 85/374/EEC of 25 July 1985 concerning liability for defective products

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Council Directive 1999/93/EC of 13 December 1999 on a Community framework for electronic signatures

Council Directive 2002/58/EC of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications

Regulation (EC) No. 593/2008 of 17 June 2008 on the law applicable to contractual obligations (Rome I)

Regulation (EC) No. 864/2007 on the law applicable to non-contractual obligations (Rome II)

Germany

Digital Signature Act 2001

German Civil Code

Teleservices Data Protection Act 1997

Teleservices Act 2002

Hong Kong

Basic Law of the Hong Kong Special Administrative Region

Crimes Ordinance (Cap 200)

Electronic Transactions Ordinance (Cap 553)

Hong Kong Bill of Rights Ordinance (Cap 383)

Hospital Authority Ordinance (Cap 113)

Interception of Communications and Surveillance Ordinance (Cap 589)

Mainland Judgments (Reciprocal Enforcement) Ordinance (Cap 597)

Medical Clinics Ordinance (Cap 343)

Personal Data (Privacy) Ordinance (Cap 486)

Post Office Ordinance (Cap 98)

Prevention and Control of Disease Regulation (Cap 599A)

Telecommunications Ordinance (Cap 106)

International

ASEAN Mutual Recognition Arrangement on Medical Practitioners

ASEAN Mutual Recognition Arrangement on Nursing Services

Nuremberg Code 1947

Rome Convention on the law applicable to contractual obligations 1980

Statute of the International Court of Justice

United Nations, 'Universal Declaration of Human Rights' (1948)

- 'International Convention on the Elimination of All Forms of Racial Discrimination' (1965)
- 'International Covenant on Economic, Social and Cultural Rights' (1966)
- 'International Convention on the Elimination of All Forms of Discrimination against Women' (1979)
- 'Convention on the Rights of the Child' (1989)
- 'UNCITRAL Model Law on Electronic Commerce' (1996)
- 'Millennium Declaration' (2000)
- 'UNCITRAL Model Law on Electronic Signatures' (2001)

World Health Organization, 'The Constitution of the World Health Organization' (1946)

- 'Ottawa Charter for Health Promotion' (WHO/HPR/HEP/95.1) (WHO First International Conference on Health Promotion, Ottawa, 21 November 1986)

World Medical Association, 'Declaration of Geneva' (as amended in 2006)

- 'International Code of Medical Ethics' (as amended in 2006)

Japan

Basic Act on Establishing a Networked Society Based on Advanced Information and Telecommunications

Ministry of Health, Labour and Welfare, Health Policy Publication No. 1075 dated 24 December 1997, as revised by Health Policy Publication No. 0331020 dated 31 March 2003 and further revised on 31 March 2011

Medical Practitioners' Act

Malaysia

Computer Crime Act 1997

Digital Signature Act 1997

Telemedicine Act 1997

New Zealand

Electronic Transactions Act 2002

Russia

Constitution of the Russian Federation

Singapore

Civil Law Act 1994 (Chapter 43, Revised Edition)

Computer Misuse Act (Chapter 50A)

Criminal Procedure Code (Chapter 68)

Electronic Transactions Act 2010 (Chapter 88)

Penal Code (Chapter 224)

Private Hospitals and Medical Clinics Act (Chapter 248)

Sweden

Professional Activities in the Health and Medical Care Field Act

United Kingdom

Access to Health Records Act 1990

Computer Misuse Act 1990

Consumer Protection Act 1987

Court and Court Officers Act 1995 (Ireland)

Data Protection Act 1998

Electronic Communications Act 2000

Health Act 1999

Medical Act 1983

Pre-Action Protocol for the Resolution of Clinical Disputes

Private and Voluntary Health Care (England) Regulations 2001

Statute of Frauds Act 1677

Supply of Goods and Services Act 1982

United States of America

American Recovery and Reinvestment Act 2009

Arizona Revised Statutes

California Business and Professions Code

California Civil Code

California, Telemedicine Development Act 1996

California, Telehealth Advancement Act 2011

Code of Alabama

Code of Federal Regulations (2009)

Federal Rules of Civil Procedure

Florida Statutes (2011)

General Statutes of Connecticut (2011)

Guam, Physicians Practice Act

Health Information Technology for Economic and Clinical Health Act 2009

Health Insurance Portability and Accountability Act 1996

Idaho Statutes

Michigan Compiled Laws, Annotated

North Carolina Administrative Code

North Carolina General Statutes

Oklahoma Code 2010

Oklahoma Telemedicine Act 1997

Ohio Revised Code

Oregon, Medical Practice Act

Pennsylvania Statutes

Public Health Service Act

Reinstatement of Law (Third) of the Foreign Relations Law

Standards for Privacy of Individually Identifiable Health Information under the
Health Insurance Portability and Accountability Act 1996

List of Abbreviations

| <u>Words or Expressions</u> | <u>Descriptions</u> |
|-----------------------------|---|
| ADR | Alternative Dispute Resolution |
| Arrangement | Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排; <i>guān yú nèi dì yǔ xiāng gang tè bié xíng zhèng qū fǎ yuàn xiāng hù rén kě hé zhí xíng dāng shì rén xié yì guǎn xiá de mǐn shāng shì àn jiàn pàn jué de ān pái</i>) |
| CEPA | Closer Economic Partnership Arrangement |
| Chinese HMA Regulation 2002 | Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; <i>zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì</i>) 2002 |
| Chinese Tort Law 2010 | Tort Law of the People's Republic of China (中華人民共和國侵權責任法; <i>zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ</i>) 2010 |
| CNST | Clinical Negligence Scheme for Trusts of the National Health Service Litigation Authority, |

| <u>Words or Expressions</u> | <u>Descriptions</u> |
|-----------------------------|---|
| | England, United Kingdom |
| DICOM | Digital Imaging and Communication in Medicine |
| EC | European Commission |
| EHR | Electronic Health Records |
| EU | European Union |
| GDP | Gross Domestic Product |
| ISP | Internet Service Provider |
| IT | Information Technology |
| MRI | Magnetic Resonance Imaging |
| NHS | National Health Service, England, United Kingdom |
| NHSLA | National Health Service Litigation Authority, England, United Kingdom |
| Rome I Regulation | Regulation (EC) No. 593/2008 of The European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations |
| SIREN | The Security in Regional Networks |
| SNOMED | Systematized Nomenclature of Medicine |
| UK | United Kingdom |
| UN | United Nations |
| US | United States of America |
| USB | Universal Serial Bus |
| WHO | World Health Organization |

CHAPTER 1

Introduction

‘The political constraint on individual reach collapsed with the fall of the Berlin Wall ... the practical constraint on individual reach collapsed with the rise of the Apple and Windows-enabled, modem connected IBM PC.’

— Thomas L Friedman¹

1.1 Chapter Summary

Telemedicine serves as ‘the medium for this global workshop of caring and concern’.² While health is considered internationally as a basic right, how to improve people’s equitable access to healthcare services, especially when ‘almost all governments’ are cutting health expenditures,³ has become an important global issue. Telemedicine provides a practical solution to uphold people’s right to equitable access to healthcare services. With the advent of information technology (IT), telemedicine has expanded the possibility of cross-border healthcare services⁴ and changed the methods of communication between health practitioners and patients by breaking both territorial frontiers and professional boundaries between different health practitioners.⁵ It may improve people’s health outcomes⁶ by enhancing their access to health care especially in remote areas and upgrading the quality of healthcare services, in addition to its potential to tackle the rising healthcare expenditure.⁷ However, legal uncertainty in its applications, together with other factors, retarded the growth of telemedicine in the past decade. This chapter gives an introduction to telemedicine and briefly discusses legal barriers impeding its development.

¹ Thomas L Friedman, *The World Is Flat – The Globalized World in the Twenty-First Century* (Revised and expanded edn, Penguin Books, London 2006) 57.

² Ronald C Merrell, ‘Telemedicine in the 90’s: Beyond the Future’ (1995) 19(1) *Journal of Medical Systems* 15, 17.

³ Teresa Brennan, *Globalization and its Terrors* (Routledge, London 2003) 66.

⁴ Timothy S Jost, ‘The Globalization of Health Law: The Case of Permissibility of Placebo-based Research’ (2000) 26 (2/3) *American Journal of Law and Medicine, Health Module* 175, 175.

⁵ Patricia C Kuszler, ‘Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability’ (1999) 25 *American Journal of Law and Medicine* 297, 302-303.

⁶ Risto Roine, Arto Ohinmaa and David Hailey, ‘Assessing Telemedicine: a systematic review of the literature’ (2001) 165(6) *Canadian Medical Association Journal* 765.

⁷ Rashid L Bashshur, Timothy G Reardon and Gary W Shannon, ‘Telemedicine: A New Health Care Delivery System’ (2000) 21(1) *Annual Review of Public Health* 613, 633-634.

1.2 An Overview on Telemedicine

1.2.1 Definitions of Telemedicine

Telemedicine is ‘a bridge to the twenty-first century’ for delivery of healthcare services,⁸ and it refers to the process but not technology itself.⁹ There is no universal definition of the term ‘telemedicine’.¹⁰ Sood and colleagues reviewed a total of 104 ‘unique, legitimate and explanatory’ definitions of telemedicine¹¹ and 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).¹²

In fact, different organizations and territories interpret telemedicine in their own ways. In Malaysia, the Telemedicine Act 1997 defines telemedicine as ‘the practice of medicine using audio, visual and data communications’.¹³ In the United States (US), there is more than one definition. For instance, the American College of Physicians defines telemedicine as ‘the use of audio, video, and other telecommunications and electronic information processing technologies to provide health services or assist health care personnel at distant sites.’¹⁴ In the Oklahoma Telemedicine Act 1997, telemedicine means ‘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’, but a consultation through telephone or facsimile machine is expressly excluded from this statutory definition.¹⁵ The Department of Commerce refers to telemedicine as ‘the use of electronic communication and information technologies to provide or support

⁸ Judith F Daar and Spencer Koerner, ‘Telemedicine: Legal and Practical Implications’ (1997) 19(3) Whittier Law Review 3, 3.

⁹ Richard Wootton, ‘Telemedicine: A Cautious Welcome’ (1996) 313(7069) British Medical Journal 1375, 1375.

¹⁰ Deborah C Baker and Lynn F Bufka, ‘Preparing for the Telehealth World: Navigating Legal, Regulatory, Reimbursement, and Ethical Issues in an Electronic Age’ (2011) 42(6) Professional Psychology: Research and Practice 405, 405.

¹¹ Sanjay Sood, Victor Mbarika, Shakhina Jugoo, Reena Dookhy, Charles R Doarn, Nupur Prakash, and Ronald C Merrell, ‘What Is Telemedicine? A Collection of 104 Peer-Reviewed Perspectives and Theoretical Underpinnings’ (2007) 13(5) Telemedicine and e-Health 573, 574.

¹² Ibid 575.

¹³ Malaysia, The Telemedicine Act 1997, section 2.

¹⁴ American College of Physicians, ‘Telemedicine Glossary’.

<<http://www.acponline.org/computer/telemedicine/glossary.htm#T>> accessed 24 December 2007.

¹⁵ §36-6802.

clinical care at a distance’.¹⁶ The Food and Drug Administration gives a broader definition as follows:

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.¹⁷

In Europe, the definition of telemedicine has changed over time. The European Commission (EC) initially defined it in 1993 as ‘the rapid access to shared and remote medical expertise by means of telecommunications and information technologies, no matter where the patient or the relevant information is located’,¹⁸ and later revised it as ‘the use of modern information and communication technologies to meet the needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers’ when the EC adopted the terminology of ‘eHealth’ to replace ‘telemedicine’ in 2003.¹⁹ In the international context, the World Health Organization (WHO) defines telemedicine as

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

¹⁶ United States, Department of Commerce, National Telecommunications and Information Administration. *Telemedicine Report to Congress* (January 31, 1997) Executive Summary [3].

¹⁷ Peter S Reichertz and Naomi Joy Levan Halpern, ‘FDA Regulation of Telemedicine Devices’ (1997) 52 Food and Drug Law Journal 517, 517.

¹⁸ European Health Telematics Association, ‘Sustainable Telemedicine: Paradigms for Future-proof Healthcare - A Briefing Paper’ (Version 1.0, 20 February 2008) 3 [3.1]
<<http://www.ehtel.org/references-files/task-force-telemedicine/ehetel-briefing-paper-sustainable-telemedicine.pdf>> accessed 19 March 2012.

¹⁹ European Commission, ‘Ministerial Declaration’ (eHealth 2003 conference, Brussels, 22 May 2003) [1].

continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities.²⁰

1.2.2 Different Terminologies of Telemedicine

Not only do the definitions of telemedicine vary, but there was also confusion in the terminologies for ‘telemedicine’, ‘telehealth’ and ‘ehealth’ in the early years,²¹ which are overlapping concepts in the context of electronic health care.²² For instance, a university in Australia defines ‘e-health’ as ‘the combined use in the health sector of electronic communication and information technology ... for clinical, educational and administrative purposes, both at the local site and at a distance’²³ and considers ‘telehealth’ a subset of ‘e-health’ comprising not only IT applications for diagnostic and treatment services, but also educational and support services as well as healthcare systems such as health information management and decision support systems. It further treats ‘telemedicine’ as a sub-subset of ‘telehealth’ to provide only medical diagnostic and treatment services.²⁴ The World Health Assembly, the supreme decision-making body for the WHO,²⁵ used ‘eHealth’ in the resolutions of its 58th Assembly in 2005.²⁶

Telemedicine also facilitates applications of other innovative medicine over the Internet. New terms such as ‘cybermedicine’, ‘Internet medicine’ or ‘online medicine’ arise to refer to situations where people solicit personalized healthcare information from a health practitioner via the Internet.²⁷ Cybermedicine, for instance, has ever been treated as a successor of telemedicine. Villanueva J sitting on the

²⁰ World Health Organization, WHO Group Consultation on Health Telematics, *A Health Telematics Policy in Support of WHO's Health-for-All Strategy for Global Health Development* (WHO/DGO/98.1, 1998) 10.

²¹ Richard E Scott, ‘Global e-health policy: from concept to strategy’ in Richard Wootton, Nivriti G Patil, Richard E Scott, and Kendall Ho (eds), *Telehealth in the Developing World* (The Royal Society of Medicine Press, United Kingdom 2009) 57.

²² Marlene M Maheu, Pamela Whitten and Ace Allen, *E-health, Telehealth and Telemedicine: A Guide to Start-up and Success* (1st edn, Jossey-Bass, San Francisco 2001) 2-4.

²³ Australia, Monash University, *Potential Telehealth Benefits of High Speed Broadband* (2011) 3 <http://www.dbcde.gov.au/_data/assets/pdf_file/0009/145584/Potential-telehealth-benefits-of-high-speed-broadband.pdf> accessed 10 April 2012.

²⁴ Ibid.

²⁵ World Health Organization, ‘Fifty-eighth World Health Assembly’ (Geneva, Switzerland, 16-25 May 2005) <<http://www.who.int/mediacentre/events/2005/wha58/en/>> accessed 12 January 2011.

²⁶ World Health Organization, ‘WHA58.28 eHealth’ (The 58th World Health Assembly, Geneva, Switzerland, 16-25 May 2005) <http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf> accessed 12 January 2011.

²⁷ Lynn D Fleisher and Meenakshi Datta, ‘Telemedicine: Legal and Regulatory Issues’ in Lynn D Fleisher and James C Dechene (eds), *Telemedicine and e-health law*, Release 9 (Law Journal Press, New York [2004] - <2009>) 1-7 §1.02[1][b].

Superior Court of New Jersey in *Allstate Insurance Co. v Northfield Medical Center, P.C.* said, ‘Cybermedicine, though a radical innovation, did not hit the market without a predecessor. A practice known as “telemedicine” paved the way for medicine practi[s]ed over the Internet.’²⁸ To tally with the rapid proliferation of technology, another set of new terms such as ‘mhealth’ (mobile health) and ‘mobile telemedicine’ have emerged recently²⁹ to describe applications of mobile technology in health services such as the use of a smart-phone to improve self-managed pulmonary rehabilitation³⁰ or combat HIV/AIDS.³¹ The mobile applications may have essentially addressed the previous worry of Sanders and Bashshur in the 1990s that the need of a physical consultation room at each end of a telemedicine consult could not maximize the benefits of telemedicine.³² As in the case of telemedicine, there are no official definitions for these terms, either. Wiesemann defines cybermedicine as ‘the Internet driven practice of medicine where patients communicate with physicians (cyberdoctors) through electronic mail, and then the cyberdoctors diagnose the patient’s ailments’,³³ and Solez and Katz refer to cybermedicine as ‘the discipline of applying the Internet to medicine’.³⁴ With regard to mhealth, Istepanian and colleagues describe it as the ‘emerging mobile communications and network technologies for healthcare’,³⁵ and the mHealth Summit organized by the Foundation for the National Institutes of Health in the US states it as ‘the delivery of healthcare services via mobile communication devices’.³⁶ Following the further advancement of technology and increase in consumer-driven Internet health applications, Stamm has

²⁸ Not Reported in A.2d, 2001 WL 34779104, 35 (N.J. Super. L., 2001) (Superior Court of New Jersey).

²⁹ ‘Innovative Uses of Technology to Improve Health for Poor and Vulnerable People to be Explored at Rockefeller Foundation Conference’ *Medical Devices & Surgical Technology Week* (Atlanta, 22 June 2008).

³⁰ A Marshall, O Medvedev and A Antonov, ‘Use of a Smartphone for Improved Self-Management of Pulmonary Rehabilitation’ (2008) 2008(Article ID 753064) *International Journal of Telemedicine and Applications*.

³¹ William Mapham, ‘Mobile phones: changing health care one SMS at a time’ (2008) (spring) *Southern African Journal of HIV Medicine* 11, 15.

³² Jay H Sanders and Rashid L Bashshur, ‘Challenges to the Implementation of Telemedicine’ (1995) 1(2) *Telemedicine Journal* 115, 122.

³³ Ranney V Wiesemann, ‘On-Line or On-Call? Legal and Ethical Challenges Emerging in Cybermedicine’ (1999) 43 *Saint Louis University Law Journal* 1119, 1119.

³⁴ Kim Solez and Sheila Moriber Katz, ‘Mainstream Medicine by 2020/Crossing Boundaries’ (2001) 19 *John Marshall Journal of Computer & Information Law* 557, 557.

³⁵ Robert S H Istepanian, Constantinos S Pattichis, and Swamy Laxminarayan, ‘Ubiquitous M-Health Systems and the Convergence Towards 4G Mobile Technologies’ in Robert S H Istepanian, Swamy Laxminarayan, and Constantinos S Pattichis (eds), *M-Health: Emerging Mobile Health Systems* (Springer 2005) 3.

³⁶ Carol Torgan, ‘The mHealth Summit: Local & Global Converge’ (*Kinetics*, 6 November 2009) <<http://www.caroltorgan.com/mhealth-summit/>> accessed 12 January 2011.

anticipated that people may soon discard the terminologies of telemedicine, telehealth or ‘tele-what-have-you’ in health services, as the global infusion of technology in health care has inevitably made it difficult to carve out the ‘tele’ element.³⁷

1.2.3 Definition of ‘Cross-border Practices’

‘Cross-border’ is an adjective referring to ‘between different countries’ or ‘involving people from different countries’.³⁸ In the practice of telemedicine, the Federation of State Medical Boards of the US, which is a national non-profit organization representing 70 medical and osteopathic boards in the US, gave a definition of ‘across state lines’ practices as follows:

The practice of medicine across state lines is defined to include any medical act that occurs when the patient is physically located within the state and the physician is located outside the state. Any contact that results in a written or documented medical opinion and that affects the diagnosis or treatment of a patient constitutes the practice of medicine. This is true whether the physician and patient are connected through telecommunications or whether patient data (such as X-rays, EKGs, or laboratory tests) are transported by courier services or in some other manner.³⁹

1.2.4 Terminologies Used in This Thesis

Owing to space constraint, it is beyond the scope of this research to dig further into any analyses on the definitions of telemedicine or any semantic debates on the above terminologies. For the avoidance of doubt, the term ‘telemedicine’ bearing the definition of the WHO given above is used throughout this thesis and interchangeably with ‘telehealth’, ‘ehealth’, ‘cybermedicine’, ‘Internet medicine’,

³⁷ B Hudnall Stamm, ‘Modeling Telehealth and Telemedicine: A Global Geosociopolitical Perspective’ (Proceedings of the 26th Annual International Conference of the IEEE EMBS, San Francisco, United States, 1-5 September 2004) 3072.

³⁸ *Cambridge Advanced Learner’s Dictionary* (1st edn Cambridge University Press, Cambridge, United Kingdom 2003) 292.

³⁹ Federation of State Medical Boards of the United States, *A Model Act to Regulate the Practice of Medicine Across State Lines* (Report of the Ad Hoc Committee on Telemedicine, Federation of State Medical Boards of the United States 1996) 2.

‘online medicine’, ‘mobile medicine’, ‘mhealth’ and terms alike, unless otherwise specified.

The definition of ‘across state lines’ telemedicine developed by the Federation of State Medical Boards of the US is used to define the cross-border practices between Hong Kong and China, with slight modifications that ‘physician’ is replaced by ‘health practitioner’, ‘across state lines’ is changed to ‘across territorial lines’ and ‘within the state and the physician is located outside the state’ to ‘within Hong Kong and the health practitioner is located in the Mainland China or vice versa’.

Also for the sake of simplicity, ‘medical negligence’ and ‘clinical negligence’ are used interchangeably. The term ‘health practitioners’ is used collectively to refer to doctors, dentists, nurses, midwives, pharmacists, dieticians, and physiotherapists, etc. unless a particular discipline of medical professions is specifically spelt out. A ‘health institute’ means a health authority, a health maintenance organization, a medical centre, a hospital, a clinic, or an entity alike.

1.2.5 A General Brief on the Development of Telemedicine

1.2.5.1 A Historical Review

It is difficult to trace the genesis of telemedicine⁴⁰ and the literature shows different time schedules as to when telemedicine began to emerge.⁴¹ It is generally believed that telemedicine was firstly developed in the US space-flight programmes and doctors’ pilot uses of commercial equipment.⁴² Use of telecommunication in the healthcare field could be traced back to the early 1900s and it has been gathering momentum around the world since then, which can be attributed to a few factors: (a) widely available and cheap telecommunication, (b) availability of computers at a lower cost with higher performance, (c) greater public confidence in the use of computer technology, (d) greater acceptance of the technology by health practitioners, and (e) ever improving standards in communications, video conferencing, and

⁴⁰ Bashshur, Reardon and Shannon (2000) (n 7) 615.

⁴¹ Olivia R Liu Sheng, Paul Jen-Hwa Hu, Chih-Ping Wei, Kunihiko Higa and Grace Au, ‘Adoption and Diffusion of Telemedicine Technology in Health Care Organizations: A Comparative Case Study in Hong Kong’ (1999) 8(4) *Journal of Organizational Computing and Electronic Commerce* 247, 251.

⁴² Karen M Zundel, ‘Telemedicine: History, Applications, and Impact on Librarianship’ (1996) 84(1) *Bulletin of the Medical Library Association* 71, 72.

medical disciplines.⁴³ Other non-IT factors including but not limited to enhanced service quality, more educational opportunities for health practitioners, reduction of healthcare costs, and the potential for economic growth have also facilitated the increased use of telemedicine in parallel.⁴⁴ Additional considerations such as aging populations, a changing model of health care, expanding diagnosis and treatment options, as well as urbanization and globalization have also driven the uptake of telemedicine.⁴⁵ To take the US as an example, the use of telemedicine started to grow in the late 1980s and 1990s owing to the advancement of IT, the American government's concern about provision of healthcare services to under-served areas, and the need of health care reform.⁴⁶ As a result of the above factors, telemedicine has grown 'wildly'⁴⁷ in the past few decades.

1.2.5.2 Telemedicine with Global Spotlights

Responses of different countries to the use of telemedicine are positive. In addition to the US,⁴⁸ other countries such as the UK,⁴⁹ Russia,⁵⁰ New Zealand,⁵¹ Australia,⁵² Japan,⁵³ India,⁵⁴ Taiwan,⁵⁵ and China,⁵⁶ etc. and cities like Hong Kong⁵⁷

⁴³ California Telemedicine & eHealth Center <http://www.cttconline.org/telemedicine_history.html> accessed 5 December 2005.

⁴⁴ Heather L Daly, 'Telemedicine: The Invisible Legal Barriers to the Health Care of the Future' (2000) 9 *Annals of Health Law* 73, 79.

⁴⁵ Australia, Australian New Zealand Telehealth Committee, 'Fact Sheet 6 – Telehealth: Strategic Drivers' in *National Telehealth Plan for Australia and New Zealand* (2001) 29 <[http://www.health.gov.au/internet/hconnect/publishing.nsf/content/7746B10691FA666CCA257128007B7EAF/\\$File/teleplan.pdf](http://www.health.gov.au/internet/hconnect/publishing.nsf/content/7746B10691FA666CCA257128007B7EAF/$File/teleplan.pdf)> accessed 10 April 2012.

⁴⁶ Mary Moore, 'The evolution of telemedicine' (1999) 15 *Future Generation Computer Systems* 245, 248.

⁴⁷ Stamm (n 37) 3072.

⁴⁸ Gene C Wunder, 'Telemedicine: An Overview' (1997) 1(2) *Proceedings of the Academy of Information and Management Sciences* 40, 40-41 (Maui, Hawaii, United States, 1997).

⁴⁹ Robert S H Istepanian, 'Telemedicine in the United Kingdom: Current Status and Future Prospects' (1999) 3(2) *IEEE Transactions on Information Technology in Biomedicine* 158.

⁵⁰ Boris A Kobrinskiy, 'Telemedicine in Russia' (2006) 23(10) *The British Journal of Healthcare Computing & Information Management* 13.

⁵¹ Karolyn Kerr and Tony Norris, 'Telehealth in New Zealand: current practice and future prospects' (2004) 10(Supplement 1) *Journal of Telemedicine and Telecare* 60.

⁵² B L Crowe, and I G McDonald, 'Telemedicine in Australia, Recent Development' (1997) 3(4) *Journal of Telemedicine and Telecare* 188.

⁵³ Takashi Hasegawa and Sumio Murase, 'Distribution of Telemedicine in Japan' (2007) 13(6) *Telemedicine and e-Health* 695.

⁵⁴ Amrita Pal, Victor W A Mbarika, Fay Cobb-Payton, Pratim Datta, and Scott McCoy, 'Telemedicine Diffusion in a Developing Country: The Case of India (March 2004)' (2005) 9(1) *IEEE Transactions on Information Technology in Biomedicine* 59.

⁵⁵ Paul Jen-Hwa Hu, Chih-Ping Wei and Tsang-Hsiang Cheng, 'Investigating Telemedicine Developments in Taiwan: Implications for Telemedicine Program Management' (Proceedings of the 35th Hawaii International Conference on System Sciences, Hawaii, United States, 2002).

have also used this type of communication technology for health care purposes. In the UK, England has treated telemedicine as a national strategy to modernize the National Health Services,⁵⁸ and the Welsh government has promised to use telemedicine round the clock to enhance access to services in rural areas.⁵⁹ China has also planned to ‘exert greater efforts’ to promote telemedicine as a means to uplifting the development of education, health and culture in rural areas.⁶⁰ To cite a few more examples, the South African government is committed to providing basic health care to all its citizens as a fundamental right through telemedicine as one of the strategic tools to enhance ‘delivery of equitable healthcare and educational services.’⁶¹ The Nigerian government launched its Telemedicine and eHealth Programme in 2005 and remarked that ‘telemedicine and eHealth services could be an economic means of achieving national health policy objectives [of developing countries] with regard to improvement and/or extension of health care to remote areas.’⁶² In Pakistan, telemedicine emerged in 1998 and has since then become an alternative to the expensive and time-consuming improvement of health infrastructure and construction of hospitals in its rural areas.⁶³

⁵⁶ Richard K C Hsieh and others, ‘Telemedicine in China’ (2001) 61(2) International Journal of Medical Informatics 139.

⁵⁷ Peter Ko, ‘Telemedicine in Hong Kong’

<<http://www2.telemedtoday.com/articles/telemedicinehongkong.shtml>> accessed 12 January 2011.

⁵⁸ United Kingdom, NHS Executive, *Information for Health: An Information Strategy for the Modern NHS 1998-2005* (The NHS Executive, United Kingdom 1998) [5.5].

⁵⁹ General Medical Council of the United Kingdom, ‘Chief Executive Report’ (14 December 2011) 10 [48] <http://www.gmc-uk.org/3_Cheif_Executive_s_Report.pdf_46311440.pdf> accessed 15 February 2012.

⁶⁰ China, 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) (‘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)’; *zhōng gòng zhōng yāng · guó wù yuàn guān yú jiā dà tǒng chóu chéng xiāng fā zhǎn lì dù jìn yī bù hāng shí nóng yè nóng cūn fā zhǎn jī chǔ de ruò gān yì jiàn* (2009 nián 12 yuè 31 rì, zhōng fā [2010] 1 hào)), [14].

⁶¹ Jill Fortuin Abrahams, ‘Telemedicine Platform’

<<http://www.mrc.ac.za/telemedicine/telemedicine.htm>> accessed 11 January 2011.

⁶² World Health Organization, Regional Office for Africa, ‘Nigeria Hosts Pan African Conference on Telemedicine and eHealth’ (2006)

<<http://www.who.int/countries/nga/mediacentre/releases/2006/ehealth/en/index.html>> accessed 11 January 2011.

⁶³ Niamat Ullah, Pervez Khan, Najnin Sultana and Kyung Sup Kwak, ‘A Telemedicine Network Model for Health Applications in Pakistan: Current Status and Future Prospects’ (2009) 3(3) International Journal of Digital Content Technology and its Applications 149, 150-151.

1.2.5.3 Applications of Telemedicine

Applications of telemedicine are emerging. In its simplest form, telemedicine involves patients' use of telephone to consult a doctor.⁶⁴ Following the rapid advances of technologies, telemedicine is evolving over time, and new uses of IT in healthcare services are continuously devised.⁶⁵ For instance, in traditional Chinese medicine but in the tele-context, recent research has proposed a new set of Chinese raw free-text clinical records to help automatic diagnosis.⁶⁶ Blum succinctly summarizes four medical uses of the Internet: access to an electronic encyclopaedia through medical websites where people secure health information, uniting users worldwide who are interested in the same medical topics, e-health transactions such as sales of healthcare products and doctors' prescription of drugs, and the actual delivery of health care for diagnoses or treatments.⁶⁷

There are in general three broad categories of telemedicine: 'store-and-forward' mode, real-time interactions, and remote surgery.⁶⁸ Research has revealed that the current applications of telemedicine are mostly made in the first two patterns.⁶⁹ With the 'store-and-forward' technology, patients' clinical information, demographic data, and digital images such as images of X-rays, computerized tomography scans and magnetic resonance imaging, etc.⁷⁰ are stored for medical archives and forwarded through telecommunication means to another location for peer or specialists consultation.⁷¹ The real-time interactive technology facilitates health practitioners in one location to conduct face-to-face consultations with patients or remote monitoring of patients⁷² in other locations through a virtual environment.

⁶⁴ Wootton (1996) (n 9) 1375.

⁶⁵ Bashshur, Reardon and Shannon (2000) (n 7) 615.

⁶⁶ Yaqiang Wang, Zhonghua Yu, Yongguang Jiang, Yongchao Liu, Li Chen and Yiguang Liu, 'A framework and its empirical study of automatic diagnosis of traditional Chinese medicine utilizing raw free-text clinical records' (2012) 45(2) *Journal of Biomedical Informatics* 210.

⁶⁷ John D Blum, 'Internet Medicine and the Evolving Legal Status of the Physician-Patient Relationship' (2003) 24(4) *The Journal of Legal Medicine* 413, 413-418.

⁶⁸ Daar and Koerner (n 8) 6.

⁶⁹ Bill Gillette, 'Telecommunications Technology Makes Its Mark on Healthcare Delivery' (2003) 13(8) *Managed Health Executive* 36, 36.

⁷⁰ Rajasvaran Logeswaran and Chikkannan Eswaran, 'Model Based Compression for 3D Medical Images Stored in the DICOM Format' (2006) 30(2) *Journal of Medical Systems* 133, 133.

⁷¹ Garehatty Kanthraj and Chakravarty Srinivas, 'Store and forward teledermatology' (2007) 73(1) *Indian Journal of Dermatology, Venereology and Leprology* 5.

⁷² Massimo Santini, Renato P Ricci, Maurizio Lunati, Maurizio Landolina, Giovanni B Perego, Maurizio Marzegalli, Milena Schirru, Chiara Belvito, Roberto Brambilla, Giuseppe Guenzati, Serena Gilardi and Sergio Valsecchi, 'Remote Monitoring of Patients with Biventricular Defibrillators through the CareLink System Improves Clinical Management of Arrhythmias and Heart Failure Episodes' (2009) 24(1) *Journal of Interventional Cardiac Electrophysiology* 53.

Health practitioners are not required to travel a long time to see patients. Through the use of remote telemedical services, special care is also enabled and made common and more accessible to patients like veterans living in remote or suburban areas.⁷³ Applications of this real-time technology include, for example, health care for home-bound patients in urban-to-rural⁷⁴ or homecare⁷⁵ situations through some devices such as a TV-based personal telehealth patient monitoring system which transmits daily and personalized patient interactions and allows patients to receive medical reminders and messages as well as diagnostic data like blood pressure and glucose levels.⁷⁶

Contemporary applications of telemedicine are far more than the above-mentioned remote patient monitoring. They include telesurgery and robotics,⁷⁷ teleradiology,⁷⁸ telepathology,⁷⁹ telepsychiatry,⁸⁰ teledermatology,⁸¹ teleambulance service,⁸² transmission of patient data,⁸³ video conferencing,⁸⁴ and telehealth education,⁸⁵ etc. Recent examples of applications in the mobile context include 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

⁷³ Adam Darkins, 'Changing the Location of Care: Management of Patients with Chronic Conditions in Veterans Health Administration Using Care Coordination/Home Telehealth' (2006) 43(4) *Journal of Rehabilitation Research and Development* vii, viii.

⁷⁴ Madan Dharmar and others, 'Telemedicine for Children in Need of Intensive Care' (2009) 38(10) *Pediatric Annals* 562.

⁷⁵ M W Raad and L T Yang, 'A Ubiquitous Smart Home for Elderly' (2009) 11(5) *Information Systems Frontiers* 529.

⁷⁶ L Schmitt, T Falck, F Wartena and D Simons, 'Towards Plug-and-Play Interoperability for Wireless Personal Telehealth Systems' (2007) 13 IFMBE Proceedings (4th International Workshop Wearable & Implantable Body Sensor Networks) 257, 257.

⁷⁷ Charles R Doarn, Kevin Hufford, Thomas Low, Jacob Rosen and Blake Hannaford, 'Roundtable Discussion: Telesurgery and Robotics' (2007) 13(4) *Telemedicine and e-Health* 369.

⁷⁸ Peeter Ross, Ruth Sepper and Hanna Pohjonen, 'Cross-border teleradiology – Experience from two international teleradiology projects' (2010) 73(1) *European Journal of Radiology* 20.

⁷⁹ B Molnar, L Berczi, C Diczazy, A Tagscherer, S V Varga, B Szende and Z Tulassay, 'Digital slide and virtual microscopy based routine and telepathology evaluation of routine gastrointestinal biopsy specimens' (2003) 56(6) *Journal of Clinical Pathology* 433.

⁸⁰ P McLaren, J Ahlbom, A Riley, A Mohammedali and M Denis, 'The North Lewisham telepsychiatry project: beyond the pilot phase.' (2002) 8(Suppl 2) *Journal of Telemedicine and Telecare* 98.

⁸¹ R Wootton, S E Bloomer, R Corbett, D J Eedy, N Hicks, et al., 'Multicentre randomised control trial comparing real time teledermatology with conventional outpatient dermatological care: Societal cost-benefit analysis' (2000) 320(7244) *British Medical Journal* 1252.

⁸² M Adeyinka, 'The teleambulance' (1996) 2(Suppl 1) *Journal of telemedicine and telecare* 76.

⁸³ Jean-François Lesesve and Richard Garand, 'Evaluation of a Telemedicine System for the Transmission of Morpho/Immunological Data Aiming at the Inclusion of Patients in a Therapeutic Trial' (2009) 2009(Article ID 767145) *International Journal of Telemedicine and Applications* 1.

⁸⁴ Cynthia LeRouge, Monica J Garfield, and Alan R Hevner, 'Quality Attributes in Telemedicine Video Conferencing' (2002) (Proceedings of the 35th Hawaii International Conference on System Sciences, Hawaii, United States, 2002).

⁸⁵ Kuszler (n 5) 299-300; See also Michael Tremblay, *Telemedicine: Legal Issues – A policy overview paper* (Rainmaker Publications 1997) 7.

through the use of mobile devices,⁸⁶ the successful use of a computerized short messaging service programme to send auto-transmitted reminders to health practitioners and inform them of possible patient delay to reduce patients' length of stay in an emergency department,⁸⁷ and the use of a game console to develop a m-health system for remote patient monitoring by an ambulance, a nursing home or a general hospital.⁸⁸ The applications of telemedicine may also be extended to extreme situations such as wars,⁸⁹ civil and natural disasters, terrorism, and other extreme environments like expeditions and desert adventures.⁹⁰ In Hong Kong, telemedicine was used to help patients in a civil disaster as early as 1998.⁹¹

In addition to medical applications, telemedicine has also been considered in court as a factor to decide the future medical expenses in the award of damages. In *Williams v Thomas Development (1989) Corp. of Canada*,⁹² Dymond J sitting on the Newfoundland and Labrador Supreme Court said, 'In assessing this head of damage, I am taking into consideration that there has been in the last 10 to 15 years major advances in the field of medicine, telecommunications and teleconferencing. These advances will continue in telemedicine and the need for costly trips to centers outside of Newfoundland will hopefully be reduced in the future.'

⁸⁶ 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).

⁸⁷ Min Joung Kim, Joon Min Park, Sang Mo Je, Je Sung You, Yoo Seok Park, Hyun Soo Chung, Sung Phil Chung and Hahn Shick Lee, 'Effects of a short text message reminder system on emergency department length of stay' (2012) 81(5) *International Journal of Medical Informatics* 296.

⁸⁸ SangJoon Lee, Jungkuk Kim and Myoungho Lee, 'The Design of the m-Health Service Application Using a Nintendo DS Game Console' (2011) 17(2) *Telemedicine and e-Health* 124.

⁸⁹ Jesse C Edwards and Camille A Motta, 'Telemedicine and the Military' in Rashid L Bashshur, Jay H Sanders and Gary W Shannon (eds), *Telemedicine: Theory and Practice* (Charles C Thomas Publisher, United States 1997).

⁹⁰ Ronald C Merrell, Stephen W Cone, and Azhar Rafiq, 'Telemedicine in Extreme Conditions: Disasters, War, Remote Sites' in Rifat Latifi (ed), *Current Principles and Practices of Telemedicine and e-Health* (IOS Press, Amsterdam, Netherlands 2008).

⁹¹ R A Cocks, 'The medical management of civil disasters in Hong Kong' (2000) 7(3) *Hong Kong Journal of Emergency Medicine* 179, 183.

⁹² 2006 NLTD 44, 254 Nfld & PEIR 61, 764 APR 61 (Newfoundland and Labrador Supreme Court) [362].

1.3 Telemedicine as a Means to Enhancing People's Right to Access to Health Services

1.3.1 Health as a Fundamental Human Right

1.3.1.1 A General Review

In common parlance, 'health' refers to 'the state of being free from illness or injury'⁹³, but it bears a wider meaning in the perspective of international public health. The WHO defines health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity',⁹⁴ and later adds that '[h]ealth is seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities'.⁹⁵ Health as a basic right was not an international concern until the first International Sanitary Conference in Paris in 1851. It became a global issue when the United Nations (UN) and the WHO were established in 1946.⁹⁶ A number of international,⁹⁷ regional,⁹⁸ and national⁹⁹ instruments have been concluded to declare health as a fundamental right in different contexts.

⁹³ *The New Oxford Dictionary of English* (1st edn, Oxford University Press, New York 2001) 846.

⁹⁴ World Health Organization, 'The Constitution of the World Health Organization' (1946), Preamble.

⁹⁵ World Health Organization, 'Ottawa Charter for Health Promotion' (WHO/HPR/HEP/95.1) (WHO First International Conference on Health Promotion, Ottawa, 21 November 1986).

⁹⁶ David Zakus and Andrea A Cortinois, 'Primary Healthcare and Community Participation: Origins, Implementation, and the Future' in Bruce J Fried and Laura M Gaydos (eds), *World Health Systems – Challenges and Perspectives* (Health Administration Press, USA 2002) 41.

⁹⁷ International treaties include, for instance, the WHO Constitution (Preamble), the Universal Declaration of Human Rights (art 25(1)), the International Covenant on Economic, Social and Cultural Rights (art 12), the International Convention on the Elimination of All Forms of Racial Discrimination (art 5(e)(iv)), the Convention on the Rights of the Child (arts 24(1) and (3)), the Convention on the Elimination of All Forms of Discrimination against Women (arts 10(h), 11(1)(f) and 12(1)), and the Declaration of Alma-Ata (Declaration I).

⁹⁸ Examples of regional instruments are the European Social Charter (art 11), the Constitution of the Russian Federation (arts 41 and 42), and the African Charter on Human and Peoples' Rights (arts 16(1) & (2); see Organization of African Unity, 'African Charter on Human and People's Rights' (1982) 21 International Legal Materials 58, 61).

⁹⁹ National instruments include, for instance, the Additional Protocol to the American Convention on Human Rights in the Areas of Economic, Social and Cultural Rights (art 10(1); see Organization of American States, *Basic Documents Pertaining to Human Rights in the Inter-American System* (Updated to July 2003) (The Ministry for Foreign Affairs of the Republic of Finland 2003) 83), and the majority of constitutions of European countries such as Italy, Belgian, Dutch, and Spain, etc. (see João Arriscado Nunes, Marisa Matias and Ângela Marques Filipe, 'Emerging Modes of Enacting Health' (Centre for Social Studies, University of Coimbra, Portugal 2006) 4)

1.3.1.2 Hong Kong

The right to health is not expressly protected in the Basic Law of Hong Kong.¹⁰⁰ Hsu argued that the Hong Kong Government assumes a constitutional duty to ensure this right for its citizens and such right is implied in articles 144 and 145 of the Basic Law that the government has to maintain its subvention policy for non-governmental organizations in, inter alia, medicine and health practised in Hong Kong, and formulate its own policies for developing and improving the social welfare system.¹⁰¹ In fact, it has been a long-established public healthcare policy that those who cannot afford private health can still receive adequate healthcare care.¹⁰² This policy is further spelt out in the Hospital Authority Ordinance where it states that the Hospital Authority of Hong Kong, a statutory entity accountable to the Hong Kong Government and responsible for managing public hospitals and their services,¹⁰³ must recommend appropriate fee policies to the government for the use of public hospital services, ‘having regard to the principle that no person should be prevented, through lack of means, from obtaining adequate medical treatment’.¹⁰⁴

1.3.1.3 China

In China, people’s rights to enjoy life and health are protected by its Constitution¹⁰⁵ that ‘[c]itizens of the People’s Republic of China have the right to material assistance from the state and society when they are old, ill or disabled’ and such rights are further codified in the General Principles of the Civil Law.¹⁰⁶ Despite these constitutional and statutory rights and the fact that China has passed Japan¹⁰⁷ to

¹⁰⁰ Hong Kong, The Basic Law of the Hong Kong Special Administrative Region of the People’s Republic of China, Chapter VI.

¹⁰¹ Berry Fong Chung Hsu, ‘Constitutional Protection of a Sustainable Environment in the Hong Kong Special Administrative Region’ (2004) 16(2) Journal of Environmental Law 193, 199.

¹⁰² Hong Kong. Legislative Council, ‘Minutes of the Special Meeting’ (LC Paper No. CB(2)2151/04-05) (Special meeting of Panel on Health Services, Hong Kong, 8 March 2005) [28(a)].

¹⁰³ Hong Kong, Hospital Authority, ‘Introduction – Caring for our community’s health’ <http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=10008&Lang=ENG&Dimension=100&Parent_ID=10004> accessed 7 April 2012.

¹⁰⁴ Hong Kong, Hospital Authority Ordinance, section 4(d).

¹⁰⁵ Constitution of the People’s Republic of China (2004 Amendment) (中華人民共和國憲法 (2004 修正); *zhōng huá rén mín gòng hé guó xiàn fǎ* (2004 *xiū zhèng*)), art 45.

¹⁰⁶ General Principles of the Civil Law of the People’s Republic of China (中華人民共和國民法通則; *zhōng huá rén mín gòng hé guó mín fǎ tōng zè*), art 98.

¹⁰⁷ David Barboza, ‘China Passes Japan as Second-Largest Economy’ *The New York Times* (New York, 15 August 2010) <http://www.bdo.co.il/Uploads/dbsAttachedFiles/China_passes_Japan_15.8.10New_York_Times.pdf> accessed 7 April 2012.

become the second largest economy in the world,¹⁰⁸ the access to health services is still considered inequitable¹⁰⁹ in China in both urban¹¹⁰ and rural areas.¹¹¹

1.3.2 Right of Access to Healthcare Services

The right to health is not identical to the right of access to healthcare services. The United Nations Committee on Economic, Social and Cultural Rights has pointed out that there are two elements embedded in the right to health: freedom and entitlements. ‘Freedom’ comprises the control of one’s health and body such as the right to be free from interference by others and from torture, whilst ‘entitlements’ refers to people’s right to have an ‘equality of opportunity for [them] to enjoy the highest attainable level of health’¹¹² and allow people to get access to health facilities, goods and services without discrimination.¹¹³

The right of access to healthcare services is an important international concern. For instance, the Charter of Fundamental Rights of the European Union proclaims that ‘everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.’¹¹⁴ The Convention on Human Rights and Biomedicine of the Council of Europe requests members to take appropriate measures with a view to providing ‘equitable access to health care of appropriate quality’.¹¹⁵ The Convention on the Elimination of All Forms of Discrimination against Women requires member states to take appropriate measures to ensure, on a basis of equality of men and women,

¹⁰⁸ Wayne M Morrison, *China’s Economic Conditions* (Congressional Research Service, Library of Congress, United States 2009) 1.

¹⁰⁹ Shenglan Tang, Qingyue Meng, Lincoln Chen, Henk Bekedam, Tim Evans and Margaret Whitehead, ‘Tackling the challenges to health equity in China’ (2008) 372(9648) *The Lancet* 1493.

¹¹⁰ Nuo Wang, Christian Gericke and Huixin Sun, ‘Comparison of health care financing schemes before and after market reforms in China’s urban areas’ (2009) 4(2) *Frontiers of Economics in China* 173.

¹¹¹ Zhongliang Zhou, Jianmin Gao, Ashley Fox, Keqin Rao, Ke Xu, Ling Xu and Yaoguang Zhang, ‘Measuring the equity of inpatient utilization in Chinese rural areas’ (2011) 11 *BMC Health Services Research* 201.

¹¹² United Nations Committee on Economic, Social and Cultural Rights of the Economic and Social Council, ‘General Comment No. 14 (2000) on Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights’ (E/C.12/2000/4, CESCR General Comment 14) [8].

¹¹³ *Ibid* [12(b)].

¹¹⁴ European Union, ‘Charter of Fundamental Rights of the European Union’ (2000/C 364/01), art 35.

¹¹⁵ Council of Europe, ‘The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine’ (Oviedo, 4.IV.1997), art 3.

women's access to healthcare services.¹¹⁶ The Health Protection and Medical Care (Seafarer) Convention 1987 stipulates that each member state should ensure measures to 'provid[e] seafarers with health protection and medical care as comparable as possible to that which is generally available to workers ashore'.¹¹⁷

1.3.3 Inequitable Access to Healthcare Services in Reality

While health and access to healthcare services have been increasingly recognized as basic individual rights, and equitable access to health care has become an important social good to reflect the social, economical and political conditions of a society,¹¹⁸ the World Bank indicated that differences in health spending have resulted in global disparity in health outcomes: the national spending differed from 6% of the GDP in rich countries to less than 3% in developing countries, or US\$3,724 per capita each year in high-income countries versus US\$32 in low-income countries in 2004.¹¹⁹ The WHO also revealed that poverty is directly linked to denial of access to basic health care.¹²⁰

The degree of accessibility to healthcare services seriously impacts people's right to health. In low-income countries where the total public revenue is often less than 20% of GDP,¹²¹ poor people cannot enjoy healthy living, and preventable infectious diseases have become one of their epidemiological diseases.¹²² For instance, about one-third of South Africans and half of Sub-Saharan Africans lived on less than US\$1 per day in 2002.¹²³ Most of them lack safe drinking water, adequate sanitation, food, education, health information and professional health care.¹²⁴ As people in these low-income countries have less access to health services and modern medicine, they have a higher mortality rate and are badly prone to health risks arising from poor nutrition, high medical costs, and long distances to health

¹¹⁶ Art 12(1).

¹¹⁷ International Labour Organization, 'Health Protection and Medical Care (Seafarers) Convention 1987' (as revised by the Maritime Labour Convention 2006), art 4(b).

¹¹⁸ Jun Gao, Shenglan Tang, Rachel Tolhurst and Keqing Rao, 'Changing access to health services in urban China: implications for equity' (2001) 16(3) *Health Policy and Planning* 302, 310.

¹¹⁹ World Bank, 'World Development Indicators 2007', 38 <http://www-wds.worldbank.org/external/default/WDSPContentServer/WDSP/IB/2010/04/21/000333037_20100421013221/Rendered/PDF/541660WDI0200710Box345641B01PUBLIC1.pdf> accessed 11 January 2011.

¹²⁰ World Health Organization, *World Health Report 2000*, 4 <http://www.who.int/whr/2000/en/whr00_en.pdf> accessed 11 January 2011.

¹²¹ *Ibid* 7.

¹²² Zakus and Cortinois (n 96) 39.

¹²³ World Bank 'World Development Indicators 2007' (n 119) 36-37.

¹²⁴ *Ibid* 37.

institutes.¹²⁵ This unsatisfactory state has persisted for years and people have become more aware of this. For example, the UN's Millennium Declaration has set a goal, among others, to reduce mortality rate of children under five years by two thirds between 2000 and 2015.¹²⁶ The Declaration of Alma-Ata also found the existing inequality in people's health status between developed and developing countries as well as between different areas in the same countries 'politically, socially and economically unacceptable'.¹²⁷ Despite international concerns, the World Bank revealed that the wide disparities between the well-off countries and the poor populations have not narrowed. Deaths of children under five years in developing countries in 2007 were over 10 million, mostly owing to preventable illnesses.¹²⁸ The mortality rate of poorer children under five years is more than double when compared with the rates of children in better-off countries.¹²⁹

Access to healthcare services is not only a problem in developing countries, but an issue in developed countries as well. The difficulty in recruiting qualified health practitioners to serve in rural areas has prevented people living in remote districts from attaining adequate levels of health services.¹³⁰ In Australia, indigenous Australians suffer from greater morbidity and mortality than their urban counterparts because of difficulty in accessing primary and other healthcare services.¹³¹ In the US where trauma centers are mostly established in urban areas, car accident mortality rates in rural areas have doubled the figures in urban areas.¹³² In Canada, despite the provision of the Canada Health Act that Canadians will have a 'reasonable' access to

¹²⁵ World Bank, 'World Development Indicators 2010', 24
<<http://data.worldbank.org/sites/default/files/wdi-final.pdf>> accessed 11 January 2011.

¹²⁶ United Nations, 'Millennium Declaration' (2000) [19].

¹²⁷ International Conference on Primary Health Care (Alma-Ata, USSR, 6-12 September 1978), 'Declaration of Alma-Ata' Declaration II.

¹²⁸ World Bank 'World Development Indicators 2007' (n 119) 6.

¹²⁹ World Bank 'World Development Indicators 2010' (n 125) 54-55.

¹³⁰ Christopher Caryl, 'Malpractice and Other Legal Issues Preventing the Development of Telemedicine' (1997-1998) 12(1) *Journal of Law and Health* 173, 176.

¹³¹ R L Gruen, T S Weeramanthri, and R S Bailie, 'Outreach and improved access to specialist services for indigenous people in remote Australia: the requirements for sustainability' (2002) 56 *Journal of Epidemiol Community Health* 517, 518.

¹³² Armar Gupta and Deth Sao, 'The Constitutionality of Current Legal Barriers to Telemedicine in the United States: Analysis and Future Directions of its Relationship to National and International Health Care Reform', 7 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1549765> accessed 18 June 2011.

health services without financial or other barriers,¹³³ people in rural communities still face inequitable access to health care.¹³⁴

1.3.4 Telemedicine: Improving Inequitable Access to Healthcare Services

As one of the practical solutions, telemedicine helps narrow the above inequality by improving people's access to healthcare services.¹³⁵ It changes the communication methods between health practitioners and patients and provides healthcare services to patients in remote areas by breaking both territorial frontiers and professional boundaries between different health practitioners. It also improves service quality by providing decision-making tools, remote sensing, and collaborative patient management arrangements¹³⁶ for previously not-easily-accessible populations, and enhances discourse between patients and health practitioners.¹³⁷ Piette and colleagues, for example, found that chronically ill patients in rural areas of Honduras, a republic in Central America, were willing to participate in automated telemedicine calls for medication adherence and health status monitoring, and this finding has further provided evidence that telemedicine is well received by patients and is a 'valuable approach' to enhancing patients' access to chronic illness care.¹³⁸

1.3.5 Telemedicine: Facilitating Global People Movements

Telemedicine is not only a means to improving the existing inequitable access to health within countries, but it also meets people's movement needs under the contemporary globalizing trend. In view of increasing people movements in the wave of globalization, together with occasional country-specific incidents such as the September-11 attacks in New York in 2001 where people of Arabian countries ceased

¹³³ Canada, Canada Health Act (R.S.C., 1985, c. C-6), section 3.

¹³⁴ Penny Jennett, Andora Jackson, Kendall Ho, Theresa Healy, Arminee Kazanjian, Robert Woollard, Susan Haydt and Joanna Bates, 'The Essence of Telehealth Readiness in Rural Communities: An Organizational Perspective' (2005) 11(2) *Telemedicine Journal and e-Health* 137, 137.

¹³⁵ See, for example, Jennifer J Moffatt and Diann S Eley, 'The Reported Benefits of Telehealth for Rural Australians' (2010) 34 *Australian Health Review* 276.

¹³⁶ 'VA health care: communication and information technologies and related issues: hearing before the Subcommittee on Oversight and Investigations of the Committee on Veterans' Affairs, House of Representatives, One Hundred Third Congress, second session, July 20, 1994' (Donald A B Lindberg's statement at 85) (US Government Printing Office, Washington 1994)
<<http://www.archive.org/download/vahealthcarecomm00unit/vahealthcarecomm00unit.pdf>> accessed 26 January 2012.

¹³⁷ Kuszler (n 5) 297-302.

¹³⁸ John D Piette and others 'Access to Mobile Communication Technology and Willingness to Participate in Automated Telemedicine Calls Among Chronically Ill Patients in Honduras' (2010) 16(10) *Telemedicine and e-Health* 1030, 1039

to go to the US for medical tourism and the Great East Japan Earthquake occurred at Miyagi Prefecture in 2011 where almost all medical facilities were damaged or destroyed by a disastrous tsunami,¹³⁹ the demand for cross-border and cross-country clinical services will grow. Telemedicine provides a convenient means in these circumstances for mobile patients to seek distant healthcare services.

1.4 A Brief on Legal Issues in Telemedicine

Technological advances in medicine create opportunities for diagnostic and treatment errors which may lead to medico-legal liability concerns,¹⁴⁰ and have expanded the traditional scope of medico-legal issues. Legal issues embedded in telemedicine today may broadly be classified into three categories: (a) traditional medico-legal issues not exclusive to the digital environment, (b) issues unique to the practice of telemedicine, and (c) conflict of laws in cross-border practices.¹⁴¹ Some examples of legal issues that telemedicine may come across are given below.

Table 1 – Examples of Legal Issues in Telemedicine

| <u>Categories</u> | <u>Example of Legal Issues</u> |
|--|--|
| (a) Traditional medico-legal issues not exclusive to the digital environment | (i) Clinical negligence (ii) Licensure and credentialing (iii) Medical records and patient data protection (iv) Fraud and abuse (v) Intellectual property (vi) Antitrust (vii) Sales of drugs, medical device, and dietary supplements |
| (b) Issues unique to the practice of telemedicine | (i) Electronic signature (ii) Taxation and reimbursement of telemedicine services (iii) Self-regulation for telecommunication network service providers |

¹³⁹ Isao Nakajima, 'Cross-Border Medical Care and Telemedicine' (2012) 3(1) International Journal of E-Health and Medical Communications 46, 49 and 51-52.

¹⁴⁰ Peter D Jacobson, 'Medical Liability and the Culture of Technology' (The Project on Medical Liability in Pennsylvania, United States 2004) 1-2
http://www.pewcenteronthestates.org/uploadedfiles/wwwpewtrustsorg/reports/medical_liability/med_mal_092204.pdf accessed 5 April 2012.

¹⁴¹ Sharon R Klein and William L Manning, 'Telemedicine and the Law'
<http://www.netreach.net/~wmanning/telmedar.htm> accessed 29 November 2011.

| <u>Categories</u> | <u>Example of Legal Issues</u> |
|---|--|
| (c) Conflict of laws in cross-border telemedicine | (i) Jurisdiction of alleged medical events involved in cross-border practices of telemedicine (ii) Enforcement of judgment in cross-border lawsuits |

1.5 Barriers to Telemedicine

Health institutes may only eliminate economic, legal and social barriers to the successful introduction of a technology years after its existence.¹⁴² Telemedicine also follows this norm. It was introduced decades ago but legal and other barriers still deter its development.

1.5.1 Legal Barriers

Legal issues are a frequent concern in the applications of telemedicine,¹⁴³ as the lack of case precedents and legislation has caused uncertainty about the legal liability of practising it,¹⁴⁴ and the market can only conjecture as to whether traditional legal principles apply to the practices of telemedicine.¹⁴⁵ Medical insurers, for instance, are not certain of their susceptibility to liability of telemedicine¹⁴⁶ because of the lack of legal precedents.¹⁴⁷ In addition, most of the current medical laws worldwide were made before the emergence of telemedical practices, and telemedicine law ‘is yet to be developed in its own right and the potential legal ramifications need to be addressed.’¹⁴⁸ In the US, Tyler criticized that ‘many of the current [telemedicine] laws are underdeveloped and unstable, and pending bills are

¹⁴² Ian R Landgreen, “‘Do No Harm’: A Comparative Analysis of Legal Barriers to Corporate Clinical Telemedicine Providers in the United States, Australia and Canada” (2002) 30 Georgia Journal of International and Comparative Law 365, 366.

¹⁴³ Elisabeth Medeiros de Bustos, Thierry Moulin, and Heinrich J Audebert, ‘Barriers, Legal Issues, Limitations and Ongoing Questions in Telemedicine Applied to Stroke’ (2009) 27(Supplementary 4) Cerebrovascular Diseases 36, 36.

¹⁴⁴ Robert F Pendrak and Peter Ericson, ‘Telemedicine and the Law’ (1996a) 50(12) Health Financial Management 46, 47.

¹⁴⁵ Landgreen (n 142) 390.

¹⁴⁶ Caryl (n 130) 182.

¹⁴⁷ Robert F Pendrak and R Peter Ericson, ‘Telemedicine may spawn long-distance lawsuits’ (1996b) 100(45) National Underwriter Life & Health Financial Services Edition 44.

¹⁴⁸ P White, ‘Legal issues in teleradiology – distant thoughts!’ (2002) 75(891) The British Journal of Radiology 201, 201.

often obscure'.¹⁴⁹ In Europe, the EC identified that the major barriers prohibiting the wide use of telemedicine are the lack of awareness of patients and/or health providers, the lack of interoperability within the EC, the inappropriate legal frameworks, and the lack of reimbursement scheme,¹⁵⁰ and it has urged legal clarity to enable wider deployment of telemedicine services since 2004.¹⁵¹ Kaddu and colleagues also stressed the need to make appropriate rules and regulations in developing countries to safeguard patients' rights in telemedicine.¹⁵² Japan has presented a successful story in this regard. Article 20 of its Medical Practitioners' Act prohibits doctors' seeing patients without face-to-face consultations,¹⁵³ which restricted the development of telemedicine in Japan.¹⁵⁴ In view of this, the Ministry of Health, Labour and Welfare has issued administrative interpretations¹⁵⁵ that telemedicine will not necessarily violate article 20 of the Act. Though it is arguable as to whether such administrative interpretations have any legal basis,¹⁵⁶ telemedicine has grown rapidly throughout the nation in conjunction with the expansion of broadband networks.¹⁵⁷

Despite the commitment of the EU, the US and other countries to the wider use of telemedicine¹⁵⁸ and the successful development of telemedicine in the past decades, legal and policy barriers have essentially retarded and disrupted its growth.¹⁵⁹ Overlapping, inconsistent and inadequate regulatory frameworks and

¹⁴⁹ Jill Lynn Tyler, 'The Healthcare Information Technology Context: A Framework for Viewing Legal Aspects of Telemedicine and Teleradiology' 1 (Proceedings of the 34th Hawaii International Conference on System Sciences, Hawaii, United States, 2001).

¹⁵⁰ European Commission, Information Society and Media Directorate-General, *Report on the public consultation on eHealth Action Plan 2012-2020* (2011) 31.

¹⁵¹ European Commission, *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on 'e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area* (SEC(2004)539)' (European Commission, Brussels, 2004, COM 356).

¹⁵² Steven Kaddu, Carrie Kovarik, Gerald Gabler and H Peter Soyer, 'Tele dermatology in developing countries' in Wootton and others (2009) (n 21) 129.

¹⁵³ Kazuyuki Nakayasu and Chiaki Sato, 'Liability for Telemedicine' (2012) 3(1) International Journal of E-Health and Medical Communications 1, 2.

¹⁵⁴ The Digital Innovation Key-Infrastructure Checkup Task Force set up by the Japanese Government, 'Study-Item List: Regulations, Medical Systems, Common Practices, etc, as Factors Hindering Digital (ITC)-Innovation', item 5 'Telemedicine', as cited in Yasumitsu Tomioka, 'Legal Interpretation of Face-to-Face Consultation in Telemedicine' (2012) 3(1) International Journal of E-Health and Medical Communications 22, 25.

¹⁵⁵ Japan, Ministry of Health, Labour and Welfare, Health Policy Publication No. 1075 dated 24 December 1997, as revised by Health Policy Publication No. 0331020 dated 31 March 2003 and further revised on 31 March 2011.

¹⁵⁶ Hiroshi Juzoji, 'Legal Bases for Medical Supervision via Mobile Telecommunications in Japan' (2012) 3(1) International Journal of E-Health and Medical Communications 33, 43.

¹⁵⁷ Hasegawa and Murase (n 53) 695-696.

¹⁵⁸ de Bustos, Moulin and Audebert (n 143) 36.

¹⁵⁹ Susan E Volkert, 'Telemedicine: Rx for the Future of Health Care' (2000) 6 Michigan Telecommunications and Technology Law Review 147, 156.

technical standards imposed by governments and professional medical organizations have constrained the present and future uses of telemedicine.¹⁶⁰ Cross-border telemedicine in particular faces difficult regulatory challenges.¹⁶¹ In Austria, together with the inadequate statutory scopes embedded in the Health Telematics Act 2005 in which only provisions for the exchange, security and publication of electronic patient data are contained,¹⁶² the statutory requirement of the Physician Act 1998 for doctors to carry out health services personally and directly, which in essence means doctors' physical appearance before Austrian patients, have prohibited the growth of telemedicine.¹⁶³ Additional considerations such as reimbursement¹⁶⁴ and other legal barriers¹⁶⁵ including but not limited to licensing requirements, medical malpractice insurance coverage, uncertain legal liability, and privacy of information¹⁶⁶ have also impacted the continuous growth of telemedicine, which have to be addressed in order to facilitate the sustainability of telemedical practices.

It is no exception in China and Hong Kong. Zhao and colleagues argued that unlike other countries, 'telemedicine in China is not impeded by any laws' but its implementation has been retarded by other factors such as inconsistent healthcare conditions, different hospital systems and lack of standards.¹⁶⁷ While this argument may be true to some extent and denotes the fact that there is currently no telemedicine law in China, Zhao et al. may have ignored the fact that despite the absence of telemedicine law in other regions such as the EU, legal uncertainty is considered one of the major barriers. On the other hand, Chen and Xia have pointed out that the absence of legislation and regulations has become a major barrier impeding the development of telemedicine in China, among other factors such as the Chinese society's insufficient understanding of telemedicine, lack of organizational and human resources, and no reimbursement for telemedicine services in the health

¹⁶⁰ Gupta and Sao (n 132) 10.

¹⁶¹ R L Cleland, 'Cross-border Telemedicine: An Uncertain Future' (2002) 46 St. Louis University Law Journal 149, 156.

¹⁶² Reinhard Busse, Annette Zentner and Sophia Schlette (eds), *Health Policy Developments (Issue 6: Focus on Continuity in Care, Evaluation Techniques, IT for Health)* (Verlag Bertelsmann Stiftung, Gütersloh, Germany, 2006) 65-67.

¹⁶³ European Commission, Directorate General Information Society, *Study on the Legal Framework for Interoperable eHealth in Europe – Final Report* (SMART 2007/0059, version 1.5, Brussels, 2009) 101.

¹⁶⁴ John W Jones, 'Payment and other obstacles slow telemedicine growth' (2004) 14(3) Managed Health Executive 53, 53.

¹⁶⁵ Steven R Levine and Mark Gorman, "'Telestroke': The Application of Telemedicine for Stroke" (1999) 30 Stroke 464, 466.

¹⁶⁶ Gupta and Sao (n 132) 10.

¹⁶⁷ Junping Zhao, Zhenjiang Zhang, Huayuan Guo, Lianzhong Ren and Shifu Chen, 'Development and Recent Achievements of Telemedicine in China' (2010) 16(5) Telemedicine and e-Health 634, 635.

insurance system.¹⁶⁸ This school of legal impediment is further supported by an exploratory research studying in most of the public healthcare organizations in Hong Kong. Similar to another survey in Australia which showed that health practitioners had medico-legal concerns when they contemplated if email communications with patients would be deployed in mental health service,¹⁶⁹ this exploratory study has revealed statistically significant factors which discriminate telemedicine-practising organizations in Hong Kong from those non-practising ones, namely the collective attitude of medical staff and their perceived service risks which may hinder the physician-patient relationship, reduce patient care effectiveness, jeopardise patient privacy, and bring psychological harm to patients.¹⁷⁰

1.5.2 Other Barriers

On top of legal barriers, culture also decides whether telemedicine applications could be successfully diffused in a society. In the technological development of telemedicine, it is important to take culture into account, especially in emerging nations, where the availability of sufficient bandwidth may not be comparable to developed countries.¹⁷¹ How to obtain consent from people of other cultures is also an issue.¹⁷² Michel asked if it is appropriate for an American doctor to tell the family of an elderly cancer patient from China, Mexico, Korea or Italy that the patient's consent is required under US law and that the patient must know all information about his or her medical condition, or whether the doctor should find other alternatives to accommodate the cultural differences.¹⁷³ In Canada, a team of Ottawa doctors faced the challenges of delivering acute care for indigenous Inuit (or Eskimo as commonly known in the US) patients living in an area of 2-million square kilometres in Nunavut of the Eastern Arctic by expanding telemedicine and overcame cultural difference by relying heavily on an enthusiastic group of 500 Inuit people

¹⁶⁸ Jie Chen and Zhiyuan Xia, 'Telemedicine in China: Opportunities and challenges' in Wootton and others (2009) (n 21) 218-219.

¹⁶⁹ Matthew Cartwright and others, 'The use of email in a child and adolescent mental health service: are staff ready?' (2005) 11(4) *Journal of Telemedicine and Telecare* 199, 203.

¹⁷⁰ Paul Jen-Hwa Hu, Patrick Y K Chau and Olivia R Liu Sheng, 'Adoption of Telemedicine Technology by Health Care Organizations: An Exploratory Study' (2002) 12(3) *Journal of Organizational Computing and Electronic Commerce* 197, 214, 216 and 220.

¹⁷¹ Stamm (n 37) 3074-3075.

¹⁷² Jost (n 4) 185.

¹⁷³ Vicki Michel, 'Factoring Ethnic and Racial Differences into Bioethics Decision Making' in Lawrence A Frolik (ed), *Aging and the Law* (Temple University Press, Philadelphia, United States, 1999) 305-306.

living in Ottawa.¹⁷⁴ Nwabueze and colleagues included about 200 physicians in a survey and found that before the introduction of telemedicine, culture significantly affects individuals' intention to use the new IT technologies, but this cultural impact reduces after telemedicine is in place and people start to know it.¹⁷⁵ Monzon also advocated a cultural approach when telemedicine was introduced in Latin America.¹⁷⁶ In addition to people's culture, organizational culture also plays a role in the acceptance of telemedicine. Doktor and colleagues undertook a study in five countries and revealed that in countries with a culture of high uncertainty avoidance such as France and South Korea, organizations adopting telemedicine appeared to be more mechanistic, whereas in countries with a culture of low uncertainty avoidance such as the US and the UK, organizations using telemedicine were more organic.¹⁷⁷

There are other factors impeding the use and development of telemedicine. Language is a potential hurdle in this regard.¹⁷⁸ In the UK, a survey conducted since 2000 and covered a population of 15,000 people being involved in the 24-hour telephone helpline of a telemedicine programme in England and Wales, namely the NHS Direct, revealed that the respondents who were in the poorer socio-economic groups or with hearing or English language difficulties were the least users of the service.¹⁷⁹ Another research involving patients in a teaching hospital with onsite interpreter services also revealed that language is a barrier for hospitalized non-English patients to document their informed consent for common invasive

¹⁷⁴ Heather Kent, 'MDs get crash course in Inuit culture as young patients arrive in Ottawa' (2000) 162(10) Canadian Medical Association Journal 1481.

¹⁷⁵ Stacie N Nwabueze, Peter N Meso, Victor W Mbarika, Mengistu Kifle, Chitu Okoli and Mark Chustz, 'The Effects of Culture of Adoption of Telemedicine in Medically Underserved Communities' (Proceedings of the 42th Hawaii International Conference on System Sciences, Hawaii, United States, 2009) 9.

¹⁷⁶ Jorge E Monzon, 'The Cultural Approach to Telemedicine in Latin American Homes' (Proceedings 2000 IEEE EMBS International Conference on Information Technology Applications in Biomedicine, Arlington, Virginia, United States, 9-10 November 2000).

¹⁷⁷ Robert Doktor, David Bangert and Michael Valdez, 'Organizational Learning and Culture in the Managerial Implementation of Clinical e-Health Systems: An International Perspective' (Proceedings of the 38th Hawaii International Conference on System Sciences, Hawaii, United States, 2005) 8.

¹⁷⁸ Michel (n 173) 307.

¹⁷⁹ Emma Knowles, James Munro, Alicia O'Cathain and Jon Nicholl, 'Equity of access to health care. Evidence from NHS Direct in the UK' (2006) 12(5) Journal of Telemedicine and Telecare 262, 263.

procedures.¹⁸⁰ Berland and colleagues found that high school level or greater reading ability is required for people to surf over English health-related websites.¹⁸¹

1.6 Chapter Conclusion

This introductory chapter gives a brief overview on the global development of telemedicine and addresses its positive impact on improving people's equitable access to health care and facilitating global people movements. Although telemedicine seems to be welcomed by countries worldwide, the existence of legal uncertainty embedded in its applications and other legal barriers such as licensing requirements and reimbursements has essentially placed a stumbling block to the further growth of telemedicine.

¹⁸⁰ Yael Schenker, Frances Wang, Sarah Jane Selig, Rita Ng and Alicia Fernandez, 'The Impact of Language Barriers on Documentation of Informed Consent at a Hospital with On-Site Interpreter Services' (2007) 22(Supplement 2) *Journal of General Internal Medicine* 294.

¹⁸¹ Gretchen K Berland, Marc N Elliott, Leo S Morales, Jeffrey I Algazy, Richard L Kravitz, Michael S Broder, David E Kanouse, Jorge A Munoz, Juan-Antonio Puyol, Marielena Lara, Katherine E Watkins, Hannah Yang and Elizabeth A McGlynn, 'Health Information on the Internet. Accessibility, Quality, and Readability in English and Spanish' (2001) 285(20) *The Journal of the American Medical Association* 2612.

CHAPTER 2

An Outline of this Study

‘The entire area of medico-legal liability is so grey that there is a really urgent need to start addressing ... concerns about the legislative parameters of e-health ... At the moment, what we have is a vacuum.’

—Juanita Fernando¹⁸²

2.1 Chapter Summary

This chapter outlines the structure of this thesis, introduces its purposes, justifies the choice of a model as the legal analytical framework, addresses the scope of work, briefs the organization of different chapters, explains its significance and discusses various research methods. Limitations of this study are shared at the end of the chapter.

2.2 Purposes of this Study

‘[Telemedical applications] are expected to participate in or even integrate with the enormous health care system in China as a result of the 1997 hand over.’¹⁸³ In line with this view, this study discusses the legal implications of practising cross-border telemedicine between Hong Kong and China and places emphasis on the medico-legal liability of such practices. Its objectives are as follows:

- (a) To study the contemporary and global development of laws in telemedicine;
- (b) To identify legal issues in telemedicine and its applications;
- (c) To reflect and compare foreign legal considerations on telemedicine in the context of Hong Kong and China;
- (d) To address the rights and areas of liability of health practitioners, health institutes and patients in cross-border telemedicine practices between Hong Kong and China; and
- (e) To discuss conflict of laws and judicial jurisdiction between Hong Kong and China when telemedicine applications are to be practised

¹⁸² Australia, Official Committee Hansard, Senate, Community Affairs Legislation Committee, *Personally Controlled Electronic Health Records (Consequential Amendments) Bill 2011, Personally Controlled Electronic Health Records Bill 2011* (6 February 2012) 39.

¹⁸³ Liu Sheng and others (n 41) 272.

between the two territories with a view to the differences in common law and civil law jurisdictions, and the unique existence of ‘One Country Two Systems’ in Hong Kong.

2.3 Legal Framework for Analyses

2.3.1 No Universally Recognized Framework

A robust model of analyzing telemedicine as a new means to deliver healthcare services is not readily available. In the socio-economic perspective, critics argued that the methodologies of assessing the impact of telemedicine to the society were of low quality, underdeveloped, not meeting acceptable standards, and in a relative lack of exploration.¹⁸⁴ In the area of legal analysis of telemedicine, there is no universally recognized framework, either. In the US, Tyler suggested, among others, a framework involving (a) malpractice, (b) data privacy, confidentiality and security, (c) licensure and credentialing, and (d) reimbursement to review the legal aspects of telemedicine.¹⁸⁵ In the UK, Tremblay raised four key questions on the practice of telemedicine: (a) the adequacy of current law and the need to create new laws, (b) the likelihood of increasing litigation due to telemedicine, (c) the necessity of having an improved regulatory framework concerning healthcare industries, and (d) patients’ choice of jurisdiction and law to proceed with a cross-border telemedicine malpractice claim.¹⁸⁶ In Europe, the EC pointed out that issues on health practitioners’ right to exercise telemedicine, accreditation and authorization for them to provide these services, recognition of the practitioners’ qualifications, protection of health-related personal data, and liability raised most concerns at both the European Union (EU) and national levels.¹⁸⁷

2.3.2 The SIREN Analytical Model

With regard to the legal liability of practising telemedicine, the Security in Regional Networks (SIREN), which was a project established by the EC’s Health Telematics Applications Programme (4th Framework Programme for Research and

¹⁸⁴ A G Ekeland, A Bowes and S Flottorp, ‘Methodologies for assessing telemedicine: A systemic review of reviews’ (2012) 81 International Journal of Medical Informatics 1, 2.

¹⁸⁵ Tyler (n 149) 4.

¹⁸⁶ Tremblay (n 85) 8-10.

¹⁸⁷ European Commission, Commission Staff Working Paper on ‘Telemedicine for the benefit of patients, healthcare systems and society’ (2009, SEC(2009)943) [4.2].

Development 1994-1998), has devised a liability reference model for the legal framework to address two scenarios within an EU country or across member states: (i) situations of mobile patients who seek healthcare services miles away from their usual place of residence in the same country or in another EU state, and (ii) sharing of electronic, digital and multi-media communications among health practitioners.¹⁸⁸ Among a wealth of published literature on data protection, SIREN identified nine relevant areas of liabilities in health telematics, namely (a) medical liability, (b) patient safety, (c) data protection principles, (d) patient liability, (e) organizational liability, (f) service liability, (g) product liability, (h) contractual liability, and (i) criminal liability.¹⁸⁹ The SIREN model is considered appropriate and applicable to the present study of cross-border practice of telemedicine between Hong Kong and China, despite the original focus of SIREN being on data protection. Detailed justifications are given below.

2.3.3 Justifications on Using the SIREN Model

2.3.3.1 A Comparatively Robust Model

The SIREN model provides a comparatively robust and comprehensive liability framework for this research. Tyler's framework cited above may not fully match the purpose of a study focusing on medico-legal liability like the present thesis, as it does not include legal aspects such as service liability of technical malfunctions of the Internet system and criminal liability. Tremblay's proposition with emphasis on the regulatory side of the legal system of telemedicine is very important. However, as there are no telemedicine laws or regulations in Hong Kong and China to govern telemedicine practices, the answers to his questions on the adequacy of current law and the need to create new law and improve the healthcare regulatory framework seem to be straightforwardly affirmative. His proposition does not differentiate various liabilities in telemedicine, either, which may not sufficiently provide an analytical framework for this research. Use of the SIREN framework for the present study is justified as follows.

¹⁸⁸ O Rienhoff and others (eds), *A Legal Framework for Security in European Health Care Telematics* (IOS Press, Netherlands 2000) 87.

¹⁸⁹ Ibid 83.

2.3.3.2 Mobile Patients

The SIREN model addresses two scenarios in the EU, namely mobile patients seeking distant healthcare services from their home towns and electronic communications among health practitioners. For the first scenario, the Health ACCESS project found that there were some 130 cross-border healthcare service arrangements among the EU member states in 2006¹⁹⁰ and the reasons behind them varied. One of the examples is patients' closeness to borders where they find cross-border providers closer than national providers.¹⁹¹ In order to make 'people's lives easier' to exercise their rights in the EU, the EC proposed in the EU Citizenship Report 2010 to make widespread use of telemedicine services by 2020 to facilitate access to cross-border healthcare services and online access to their personal medical data.¹⁹²

People movement in the EU echoes the current situation between Hong Kong and China. After the change of sovereignty in 1997, people movement between the two territories has been rising tremendously. Statistics showed that the number of Hong Kong resident departures to China jumped from 61.1M in 2001 to 75.8M in 2006,¹⁹³ whilst the number of visitors from China to Hong Kong, following the introduction of the Individual Visit Scheme in 2003 as a liberalization measure to allow residents in China to stay in Hong Kong for up to seven days on each visit upon presentation of a valid exit endorsement issued by relevant authorities in China,¹⁹⁴ rocketed from 4.4M in 2001 to 13.6M in 2006¹⁹⁵ and reached a peak of 25.3M in 2011.¹⁹⁶ Also, with the Hong Kong Government's immigration policies such as the Quality Migrant Admission Scheme and the Capital Investment Entrant Scheme to

¹⁹⁰ Reinhard Busse, Markus Wörz, Thomas Foubister, Elias Mossialos and Philip Berman, *Mapping Health Services Access: National and Cross-Border Issues (HealthACCESS) (Final Report November 2006)* 6 <http://ec.europa.eu/health/ph_projects/2003/action1/docs/2003_1_22_frep_en.pdf> accessed 17 December 2011.

¹⁹¹ Ibid 5.

¹⁹² European Commission, *EU Citizenship Report 2010: Dismantling the obstacles to EU citizens' rights* (European Commission, Brussels, 2010, COM(2010) 603 final) 24.

¹⁹³ Hong Kong, Census and Statistics Department (b), 'Transport, Communications and Tourism' <http://www.censtatd.gov.hk/FileManager/EN/Content_807/transport.pdf> accessed 29 December 2007, 3 & 5.

¹⁹⁴ Hong Kong, Tourism Commission, 'Individual Visit Scheme' <http://www.tourism.gov.hk/english/visitors/visitors_ind.html> accessed 10 March 2012.

¹⁹⁵ Hong Kong, Census and Statistics Department (b) (n 193).

¹⁹⁶ Hong Kong, Census and Statistics Department (a), *Hong Kong in Figures* (2012 edn, Government Logistics Department, Hong Kong 2012) 43.

attract respectively ‘highly skilled or talented persons’¹⁹⁷ and people with a threshold of investment of HK\$10 million¹⁹⁸ (approximately US\$1.3 million) to stay in Hong Kong, the number of migrants from China is expected to shoot up. As at the end of 2010, the number of approved applications including persons from China and overseas under the Quality Migrant Admission Scheme was 1,808, whilst the corresponding number under the Capital Investment Entrant Scheme was 8,924, on top of 1,268 approvals in principle.¹⁹⁹

The reasons behind demand for cross-country and/or cross-border healthcare services are many-fold. Taking the elderly as an illustration, there is an increasing trend of more elderly Hong Kong residents residing in China to spend their last years.²⁰⁰ Under the current social policy, they have to return to Hong Kong before they can receive public medical services²⁰¹ and other elderly allowances.²⁰² Subject to the availability of appropriate government policies, telemedicine does provide a more convenient alternative for these elderly if they prefer healthcare services from Hong Kong. There are also other short-term cross-border demands for healthcare services such as the surge in demand by pregnant women from China for obstetric services in Hong Kong, which forced the Hong Kong Government to seriously assess its impact on healthcare resources and set a quota system effective from 2012 for non-local expectant mothers.²⁰³ Telemedicine as a means of delivering healthcare services through the use of IT and the Internet may be a cost-effective solution to help meet these cross-border demands between the two territories to some

¹⁹⁷ Hong Kong, Immigration Department (a), ‘Scheme Objective’

<http://www.immd.gov.hk/ehtml/QMAS_2.htm> accessed 29 November 2011.

¹⁹⁸ Hong Kong, Immigration Department (b), ‘Eligibility Criteria (Applications submitted on or after 14 October 2010)’ <http://www.immd.gov.hk/ehtml/hkvisas_13_4b.htm> accessed 29 November 2011.

¹⁹⁹ Hong Kong, Immigration Department (c), ‘Hong Kong: The Facts – Immigration (June 2011)’ <<http://www.gov.hk/en/about/abouthk/factsheets/docs/immigration.pdf>> accessed 29 November 2011, 1.

²⁰⁰ ‘A Trend may be Underway as some Elderly Hong Kong Residents go North to China to Spend their Last Years’ (‘香港人北上養老是大勢所趨’; *xiāng gǎng rén běi shàng yǎng lǎo shì dà shì suǒ qū*) *Wenweipo* (Hong Kong, 18 April 2004)

<<http://www.globalaging.org/health/world/2004/hongkong.htm>> accessed 20 December 2010.

²⁰¹ Ibid.

²⁰² Under the policy as at the time of writing this thesis, an elderly person who receives the Old Age Allowance or the Disability Allowance has to reside in Hong Kong for not less than 60 days in a payment year, which refers to the 12-month period from the date when the recipient starts to receive allowance. See Hong Kong, Social Welfare Department, ‘Social Security Allowance (SSA) Scheme’ <http://www.swd.gov.hk/en/index/site_pubsvc/page_socsecu/sub_ssallowance/> accessed 12 March 2012.

²⁰³ Hong Kong, Hong Kong Government, ‘Non-local women giving birth in Hong Kong in 2012 limited to 35,000 (Press Release 24 June 2011)’ <<http://www.info.gov.hk/gia/general/201106/24/P201106240171.htm>> accessed 28 August 2011.

extent, if not all.

2.3.3.3 Electronic Communications

The second scenario dealt with by the SIREN model, i.e. electronic communications among health practitioners, also mirrors the developments of electronic health records in Hong Kong and China. Sharing of patient data among health practitioners and institutes will not only enhance citizens' access to health services across different countries, it may also create huge financial values worldwide. For instance, IMS Health, a supplier of medical information for market research, sold patient data in over 100 countries and earned over US\$2 billion in 2006.²⁰⁴ Hong Kong and China have not yet treated patient data as a marketable asset but are improving the respective technical readiness to share patient data. The Hong Kong Government has made a 2-stage territory-wide roadmap to share electronic healthcare records between the public and private health sectors as well as the public for the purpose of supporting health care. Its first stage will be ready by 2013-14.²⁰⁵ In China, studies showed that as at 2008, 80% of specialty tertiary hospitals, general hospitals and university-affiliated hospitals were equipped with hospital information systems.²⁰⁶ The Ministry of Health of China also established a steering committee in 2008 to study the standards, policies and guidelines of national electronic health information systems.²⁰⁷ Although as of this writing, the author knows of no public policy to share patient data between hospitals in Hong Kong and China, it is anticipated that following more frequent people movement and the 'Closer Economic Partnership Arrangement' (CEPA), which is the first free trade agreement concluded by Hong Kong and China after the change of sovereignty of Hong Kong in 1997,²⁰⁸ patient-data sharing between the two territories would not be a healthcare initiative far away from the foreseeable future.

²⁰⁴ Marc A Rodwin, 'Patient Data: Property, Privacy & the Public Interest' (2010) 36(4) American Journal of Law and Medicine 586, 592

²⁰⁵ Hong Kong, Food and Health Bureau, *Electronic Health Record Engagement Initiative (EEI) - Invitation for eHR Partnership - Private Healthcare Sector* (2009) 5
<http://www.ehealth.gov.hk/en/doc/eei_int_doc_en.pdf> accessed 17 December 2011.

²⁰⁶ J Liang and others, 'Developing Interoperable Electronic Health Record Service in China' (2011) 5(4) International Journal of Digital Content Technology and its Applications 280, 281.

²⁰⁷ Ibid.

²⁰⁸ Hong Kong, Trade and Industry Department, 'Mainland and Hong Kong Closer Economic Partnership Arrangement (CEPA)' <http://www.tid.gov.hk/english/cepa/cepa_overview.html> accessed 20 December 2011.

In sum, mobile patients seeking distant healthcare services from their home towns through telemedicine are subject to similar, if not identical, medico-legal risks such as clinical negligence and medical data errors transmitted through telecommunication networks, no matter whether they are physically in the EU, the US, Hong Kong, China, or anywhere else. While the SIREN model provides a robust framework to address liability issues of mobile patients and sharing of patient data in the EU, it is submitted that it also provides a consolidated framework to examine the telemedicine practices between Hong Kong and China. The SIREN model will be employed in this research.

2.4 Scope of this Study

Availability of resources such as time and timing may limit the scope of a study, affect the methodologies used and make a study to be conducted in stages.²⁰⁹ The SIREN model, as discussed above, involves nine areas of liability.²¹⁰ It would be too ambitious for the author to cover in full detail all the nine important areas in a single doctoral research conducted on a part-time basis, with a view to the fact that the EU has taken a few years to undertake a study on the legal issues of telemedicine. In particular, the EU issued a European e-health action plan in 2004 to set out objectives to improve legal certainty²¹¹ and published a final report in 2007 on the study on the legal framework for interoperable telemedicine in Europe.²¹² It then adopted the EU Council's conclusions on safe and efficient healthcare through eHealth at the end of 2009 which called upon member states to bring legal clarity and ensure protection of health data.²¹³ It further launched a public consultation in 2011 on another e-health action plan for the period 2012-2020, trying to validate the improvement of legal certainty for ehealth as one of the objectives and explore actions in the next few years.²¹⁴

²⁰⁹ Ian Dobinson and Francis Johns, 'Qualitative Legal Research' in Mike McConville and Wing Hong Chui (eds), *Research Methods for Law* (Edinburgh University Press, Edinburgh 2007) 34.

²¹⁰ Rienhoff and others (eds) (n 188) 83.

²¹¹ European Commission (2004) (n 151) 13 and 19.

²¹² European Commission, Directorate General Information Society (2009) (n 163).

²¹³ European Union, Council Conclusions of 1 December 2009 on a Safe and Efficient Healthcare through eHealth (2009/C 302/06) 2.

²¹⁴ European Commission, Information Society and Media Directorate-General (2011) (n 150) 2.

2.4.1 Prioritization of the SIREN Liabilities

With a view to the resource constraints in this study, prioritization of the nine areas of SIREN liability has to be set out with justifications. The research question in the current study is the medico-legal liability of cross-border telemedicine practices between China and Hong Kong, and the key term is ‘medico-legal liability’. Upon the author’s consultations with legal and medical dictionaries, literature review, as well as checks for case law in various common law jurisdictions through online professional legal databases such as the Westlaw, it seems very likely that there has been no confined scope about what constitutes medico-legal liability. How should the nine SIREN liabilities be prioritized in this regard? A public consultation in Europe may provide a hint. After the aforesaid public consultation launched by the EC in 2011 to pave way for its e-health action plan 2012-2020, out of the over 200 respondents who represented different stakeholders such as non-governmental organizations, academia, enterprises, health and social care providers and public authorities from many EC member states, 68.37% expressed the view that in the legal context, it is most important for the EC to encourage professional associations, scientific societies and civil society representatives to promote the best practices through the development of guidelines and/or codes of conduct for ehealth services;²¹⁵ 57.67% thought that it is important to propose a legal framework for the EC to protect the rights of users of in cross-border telemedical practices;²¹⁶ 73.80% agreed with the objective of improving legal certainty for ehealth.²¹⁷ The respondents referred the concept of ‘legal certainty’ in the context of ehealth essentially to include issues of data protection, cross-border data transfer, provider liability and ethic issues.²¹⁸ Among these issues, data protection and liability in particular were considered the most important areas to look at.²¹⁹

A few observations can be made by comparing the nine liability elements of the SIREN model with the above consultation results, which are tabulated below:

²¹⁵ Ibid 25.

²¹⁶ Ibid 25.

²¹⁷ Ibid 24.

²¹⁸ Ibid.

²¹⁹ Ibid 26.

Table 2 – Prioritization of the SIREN Liabilities

| ‘Legal certainty’ as revealed in the 2011 EU Consultation | Corresponding SIREN liability | Remarks |
|---|--|--|
| (a) Data protection (b) Cross-border data transfer | 1. Data protection principles | |
| (c) Provider liability | 2. Medical liability 3. Patient safety 4. Organizational liability 5. Service liability 6. Product liability 7. Contractual liability | Providers include (i) Health practitioners, (ii) Health institutes, and (iii) Computer network providers. |
| (d) Ethical issues | - | Out of the scope of this study |
| - | 8. Patient liability 9. Criminal liability | |

In terms of prioritization, there are few studies, if not none, to discuss which liability should be accorded a higher priority than others. To take a ballpark approach to make an inference from the above consultation exercise, the author has taken the liberty to assume that in the eyes of the 200-strong institutional and professional respondents from the EU member states, the first seven SIREN liability issues in Table 2 above are of more important practical implications in telemedicine than the remaining two. The justifications are as follows.

First of all, the medico-legal aspect of practising cross-border telemedicine is the focus of this research. Medical liability is therefore considered the most relevant area for discussion. Besides medical liability, patient safety and patient data protection are significant issues, as health practitioners and institutes have to make proactive initiatives to safeguard patients’ best interests, irrespective of whether healthcare services are delivered traditionally or online. In addition to these areas of liability, health practitioners and institutes have to meet other duties as well. Institutional elements comprising organizational liability, service liability and product liability will then be discussed, which deal with the relationship and responsibilities of health practitioners, health institutes and third parties such as telemedicine equipment suppliers and Internet service providers (ISPs). Contract liability is also an important area from the institutional perspective, as contractual provisions may help to define the scope of liability of various parties in a telemedical practice.

As for the last two SIREN issues, namely patient liability and criminal liability, after deliberation, the author has allocated comparatively less resources to them, with a view to the trends of medico-legal lawsuits in these two areas. There are rarely claims against patients in the context of clinical negligence. Cases occasionally involved health practitioners as claimants and patients or their family members as defendants may be defamatory in nature like patients' leaving negative comments on online review sites. *Carlotti v Petta*²²⁰ in Arizona and *McKee v Luarion*²²¹ in Minnesota are two recent examples in the US.

Criminal liability is another odd man out among the nine SIREN liabilities. A health practitioner may face a charge of manslaughter if he or she has been grossly negligent.²²² Although the number of health practitioners being prosecuted in criminal proceedings has risen in recent years²²³ and Hesketh commented that '[a]lmost every other week there [was] a sensational article on the topic, usually concerning crimes committed by health professionals against patients',²²⁴ criminal actions for clinical negligence are rare and it is difficult to identify reliable statistics about prosecutions of doctors for manslaughter.²²⁵ Ferner and McDowell could only find 85 criminal prosecutions in the UK in the two centuries between 1795 and 2005.²²⁶ Zhang said that in China, 'a large number of infringement behaviors of citizen's life and health is (*sic*) not severe enough to offend against criminal law' and such cases are usually handled from the perspective of civil liability.²²⁷

To follow the logic of the foregoing paragraphs, the author has considered that the first seven SIREN liability issues listed in Table 2 require discussion at greater length in this thesis. More space is reserved for medical liability, patient safety, data protection principles, organizational liability, service liability, product

²²⁰ Case Number: CV2008-010464 (Superior Court of Arizona, Maricopa County, 14 December 2011).

²²¹ Case Number: A111154 (Minnesota Court of Appeals, 23 January 2012).

²²² See, for example, *R v Adomako (John Asare)* [1995] 1 AC 171, [1994] 3 All ER 79 (House of Lords).

²²³ Margot Brazier, 'Times Of Change?' (2005) 13(1) Medical Law Review 1, 13.

²²⁴ Wendy Hesketh, 'Medico-Crime: Time for a Police-Health Professions Protocol?' (2003) 76(2) Police Journal 121, 121.

²²⁵ Margaret Brazier and Amel Alghrani, 'Fatal medical malpractice and criminal liability' (2009) 25(2) Professional Negligence 51, 55.

²²⁶ R E Ferner and Sarah E McDowell, 'Doctors charged with manslaughter in the course of medical practice, 1795 – 2005: a literature review' (2006) 99(6) Journal of the Royal Society of Medicine 309, 312 and Table 2.

²²⁷ Yue Zhang, 'Legal Guarantees to the Right to Health in China' (張越, '中國健康權的法律保障'; *zhāng yuè*, 'zhōng guó jiàn kāng quán de fǎ lǜ bǎo zhàng') (The fifth Expert Network Seminar of the EU-China Human Rights Network, Colchester, United Kingdom, April 2004).

liability and contract liability, whilst patient liability and criminal liability will only be discussed briefly. Also, as revealed in the EU consultation exercise, professional guidelines and codes of conduct for telemedicine are considered important. The author will make use of professional guidelines and codes developed in various countries as reference where appropriate.

2.4.2 Other Topics Considered Out of the Scope of this Study

Legal barriers commonly found in the discourse on the development of telemedicine such as e-health financing, reimbursement, and taxation are considered to have no direct relevance to its medico-liability. While these issues are important considerations for the survival and sustainability of telemedicine programmes, owing to resource limitations, they are out of the scope of the present study and will not be addressed fully in this thesis.

The no-fault compensation systems of Denmark, Sweden and New Zealand etc. will not be studied in detail in this research, either, as the focus of this thesis is the medico-legal liability of practising cross-border telemedicine between Hong Kong and China, where Hong Kong is still under the traditional tort system when dealing with clinical negligence claims and China runs a civil law system. In fact, the no-fault system has been under debate for years. Its proponents iterate its advantages to compensate more claimants in a cost- and time-efficient way, whereas its opponents argue to the contrary that it will incur higher compensation costs and reduce incentives for medical precautions, thus resulting in more injuries.²²⁸ In the UK, for example, after studies on the possibility of replacing the English tort system with a no-fault scheme similar to those in Sweden and New Zealand, both the Pearson Commission²²⁹ and the Chief Medical Officer²³⁰ rejected such a system, out of considerations such as costs, practical difficulties in overhauling the tort system and running a no-fault scheme, and the compliance with article 6 of the European Convention on Human Rights. Fenn, Gray and Rickman projected that a Swedish-

²²⁸ Daniel P Kessler, Nicholas Summerton and John R Graham, 'Effects of the medical liability system in Australia, the UK, and the USA' (2006) 368(9531) *The Lancet* 240, 244.

²²⁹ Command 7054-1 [1715]; as cited in William J Gaine, 'No-fault compensation systems: Experience elsewhere suggests it is time for the UK to introduce a pilot scheme' (2003) 326(7397) *British Medical Journal* 997, 998 and Footnote 1.

²³⁰ United Kingdom, Chief Medical Officer, *Making Amends – A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS* (Department of Health, London, United Kingdom 2003) 111-113.

style no-fault system for clinical negligence claims in the National Health Service (NHS) of England would cost more than six times the expenditure under the English tort system.²³¹ In fact, the expenditure of the New Zealand Accident Compensation Scheme grew faster than inflation in the period of 1975-1997.²³² The Scheme is still facing financial problems in recent years. Its net annual deficit rose from \$103.5 million in 2004-05 to \$598.6 million in 2008-09 and the situation only improved recently with a small surplus of \$4.7 million recorded in 2009-10.²³³ Despite the aforesaid findings, Scotland proposed in 2011 introducing a no-fault accident compensation scheme for medical injuries, along the lines of the Swedish model.²³⁴ In civil law jurisdictions, the no-fault system also arouses debate. Macau inherited a civil law system from Portugal when China took its sovereignty back in 1999, but it has had no specific law enacted so far for medical negligence cases. The Macau government issued a consultation paper in 2005 proposing a no-fault system for medical claims.²³⁵ Following years of hot discussion in the society, the government finally changed its legislative direction and announced in 2012 that it would be a fault-based system.²³⁶

2.5 Organization of the Thesis

This thesis consists of three sections involving eight chapters. The first part includes three chapters: the introduction to give a general background to the development of telemedicine, the outline of the structure of this thesis, and the brief on laws in relation to clinical negligence and the impact of telemedicine to the existing law. The second section is composed of four chapters to discuss the SIREN liabilities. The last section comprises a final chapter discussing the medico-legal

²³¹ Paul Fenn, Alastair Gray and Neil Rickman, 'The Economics of Clinical Negligence Reform in England' (2004a) 114(496) *The Economic Journal* F272, F288 and F290.

²³² Cushla Thomson, Susan Begg and Bryce Wilkinson, *Accident Compensation: Options for Reform* (New Zealand Business Roundtable, Wellington, New Zealand 1998) 163.

²³³ Stephen Todd, 'Treatment Injury in New Zealand' (2011) 86(3) *Chicago-Kent Law Review* 1169, 1203.

²³⁴ Scotland, *No Fault Compensation Review Group Report and Recommendations* (Volume I) (15 February 2011) 6.

²³⁵ Macau, 'Medical Incidents Law' *Consultation Paper* (12 January 2005) (澳門, 《醫療事故法》諮詢文本 (2005 年 1 月 12 日); ào mén, '《yī liáo shì gù fǎ》 zī xún wén běn (2005 nián 1 yuè 12 rì))' <http://www.ssm.gov.mo/design/news/document/c_ccrsm_20050112.pdf> accessed 5 May 2012.

²³⁶ Macau, 'The Government will speed up the legislative work for the Medical Incidents law, with a direction towards a fault-based system' *Journal San Wa Ou* (Macau, 25 April 2012) (澳門, '政府加緊醫療事故立法 取向於有過錯醫療責任' 新華澳報 (2012 年 4 月 25 日); ào mén, 'zhèng fǔ jiā jìn yī liáo shì gù lì fǎ qǔ xiàng yú yǒu guò cuò yī liáo zé rèn' xīn huá ào bào (2012 nián 4 yuè 25 rì))' <<http://www.waou.com.mo/detail.asp?id=60197>> accessed 5 May 2012.

aspects of cross-border telemedicine between Hong Kong and China and an appendix. Throughout this thesis, international laws, national and state laws, regulations, case law, and professional guidelines from domestic and foreign sources will be studied and cross referenced.

Chapter 1 introduces a brief overview of telemedicine and legal barriers impeding its development. Chapter 2 gives an outline including purposes, analytic framework, organizational structure, scope, significance, methodology and limitations of this study. Chapter 3 briefs the legal principles of clinical negligence in various common law and civil law countries and how telemedicine will impact the current legal systems. Chapters 4 and 5 correspond to health practitioners' medical liability, covering their legal relationship with patients, duty of care in tort and contract, standard of care, proof of injury and causation. Chapters 6 and 7 relate to other areas of the SIREN liability framework, with the main focus on patients and health institutes. Patient issues consist of (a) patient safety in telemedicine, (b) patient data protection including privacy and confidentiality in the ehealth environment, and (c) patients' liability to provide necessary health data to the health practitioners.²³⁷ Institutional considerations include four components: (a) organizational liability of health practitioners and/or health institutes in telemedicine, (b) service liability arising as a result of telemedicine practices over a distance, (c) product liability in the use of telemedical devices, and (d) contractual liability. Chapter 7 also covers criminal liability such as online threats in relation to unauthorized interception to transmission of confidential information and computer hacking.²³⁸ Chapter 8 discusses medico-liability concerns in potential telemedicine lawsuits between Hong Kong and China and addresses the issues on conflict of laws and jurisdiction in view of the co-existence of common law and civil law systems as well as the unique 'One Country Two Systems' in Hong Kong after the change of sovereignty in 1997. Also, concluding remarks and the ways forward are given in this chapter. An appendix with a sample of survey letters and reminders in the author's early attempt to conduct an empirical study is attached to the end of this thesis.

²³⁷ Rienhoff and others (eds) (n 188) 105.

²³⁸ Russell G Smith, 'Telemedicine and Crime' (Australia Institute of Criminology 1997) <<http://www.aic.gov.au/documents/0/E/2/%7B0E288730-9C19-4763-B867-C018FC59D1A4%7Dti69.pdf>> accessed 12 January 2011, 1-6.

2.6 Significance of this Thesis

While telemedicine seems to be a good tool for governments to reduce medical expenses, health practitioners to deliver more efficient quality services, and patients to enjoy enhanced access to quality health care, society at large should not overlook the legal issues behind this evolutionary means of healthcare services, especially when it is to be conducted in different states of federal governments or across different countries, where laws are different from state to state and from country to country. As de Bustos, Moulin, and Audebert put it, '[c]ross-border provision of telemedicine services ... requires legal clarification on an international basis ...'²³⁹ Jost predicted that there would be globalization of health law for the next millennium.²⁴⁰ This prediction, if correctly made, would inevitably touch upon cross-border telemedicine practices, which would involve complex legal issues such as jurisdiction of courts in different countries for a clinical negligence case arising from the practice, different licensure and credentials requirements for health practitioners, new health practitioner-patient relationship, different standards of care due to technological advancement affecting the assessment of medical negligence, and protection of patients' electronic medical records, etc.

2.6.1 Insufficient Legal Attention

However, not every society pays sufficient legal attention to the growth of telemedicine. In Europe, there are no specific legal provisions to govern telemedicine in Belgium, Bulgaria, Greece, Hungary, Ireland, Lithuania, Netherlands, Scotland and Slovakia.²⁴¹ Some countries have not educated the public about what telemedicine is or deliberated legal issues sufficiently, not to mention modifying their domestic or national laws to cope with this new technology or developing new laws to safeguard the rights of patients and identify clearly liabilities of health practitioners and institutes in telemedicine applications. A survey conducted in Canada found that only 29% of the respondents knew that videoconferencing is a means of conducting medical tests and making diagnoses, 87.8% of them concerned responsibility and liability for malpractice and errors in telemedicine, and 72.1% cared about the

²³⁹ de Bustos, Moulin and Audebert (n 143) 38.

²⁴⁰ Jost (n 4) 176.

²⁴¹ European Commission, Directorate General Information Society (2009) (n 163) 98-101.

differences in healthcare rules and regulations among countries or provinces.²⁴² Hong Kong and China are no exception. Despite the developments of telemedicine since the 1990s in these two territories, no legislation is being enacted with regard to telemedicine practices in both territories. One of the most prestigious private hospitals in Hong Kong said, ‘as far as we are aware the practice of telemedicine is still in its infancy in Hong Kong and there are hardly any specific laws or regulations governing such practice.’²⁴³ A century-old faculty of medicine in Hong Kong also revealed that they did not have documentation or information on telemedicine.²⁴⁴

In fact, some countries have taken a more proactive legislative approach than others in response to the development of telemedicine. In civil-law jurisdictions, Germany was the first country in Europe to pass the Teleservices Data Protection Act in 1997.²⁴⁵ Following this legislation, others such as the Digital Signature Act and the Teleservices Act also became effective in 2001 and 2002 respectively. In common-law jurisdictions, the US federal government started to develop its national telemedicine strategy well before most Americans ever heard of telemedicine²⁴⁶ and 22 numbers of legislation relating to telemedicine were introduced in the 105th Congress (1997-1999) and 4 more were discussed in the 106th Congress (1999-2001).²⁴⁷ Oregon passed its telemedicine law in the late 1990s to create a new licence for doctors living outside Oregon but treating patients in that state.²⁴⁸ California has even taken an advanced initiative to have passed a new Telehealth Advancement Act 2011, which became effective on 1 January 2012, to update its Telemedicine Development Act 1996.²⁴⁹ Malaysia passed its Telemedicine Act for regulating the

²⁴² PricewaterhouseCoopers conducted the survey. See Shelley Martin, ‘Public ignorant about telemedicine, survey finds’ (2001) 164(7) *Canadian Medical Association Journal* 1035.

²⁴³ Private correspondence dated 8 January 2008 between the Hong Kong Sanatorium & Hospital and the author.

²⁴⁴ Private correspondence dated 18 February 2008 between the Faculty of Medicine of the University of Hong Kong and the author.

²⁴⁵ Lee A Bygrave, ‘Germany’s Teleservices Data Protection Act’ (1998) 5 *Privacy Law & Policy Reporter* 53, 53.

²⁴⁶ Caryl (n 130) 173.

²⁴⁷ Scott A Edelstein, ‘Careful telemedicine planning limits costly liability exposure’ (1999) 53(12) *Healthcare Financial Management* 63, 69.

²⁴⁸ Douglas Perednia, ‘Legal Issues: Telemedicine Poses Challenges to Lawmakers’ *Blood Weekly* (Atlanta, 18 September 2000) 8-9.

²⁴⁹ ‘California Signs Telehealth Advancement Act’ *Healthcare Informatics* (11 October 2011) <<http://www.healthcare-informatics.com/news-item/california-signs-telehealth-advancement-act>> accessed 10 May 2012.

practice of telemedicine as early as in 1997,²⁵⁰ together with other cyber laws such as the Digital Signature Act 1997 and the Computer Crime Act 1997.

There is a genuine need for Hong Kong and China to examine the medico-legal liability of health practitioners and the rights of patients before cross-border telemedicine applications will be widely practised in the foreseeable future. If health practitioners and patients in Hong Kong and China are not aware of the law and do not understand the legal impact on practising telemedicine, this will inevitably follow the experiences in other countries such as the US that the growth of telemedicine will be slowed down or even disrupted.

2.6.2 Close Relationship between Hong Kong and China

2.6.2.1 Enhanced People Movement between the Two Territories

Hong Kong and China are chosen as the study foci because of a few considerations. The first issue relates to their close political, social, economic, geographical, and cultural relationship after the change of sovereignty of Hong Kong from the UK to China in 1997, which has increased the movement of people between the two territories. Despite this close proximity, no discussion has been made on harmonization of any health laws since China's inception of Hong Kong, let alone studying the legal impact of any cross-border telemedicine practices on health practitioners and patients.

2.6.2.2 Credentials and Licensure

The second issue concerns health practitioners' credentialing and licensing. Though Hong Kong is now under the philosophy of 'One Country, Two Systems', there has only been slow progress in bilateral recognition of medical qualifications. Health practitioners in Hong Kong were not allowed to practise in China and vice versa and it was only after the signing of the second stage of CEPA between Hong Kong and China in January 2005 that doctors of Hong Kong are able to provide short-term medical services in China.²⁵¹ The first group of 14 doctors from Hong Kong went to Guangzhou, a Chinese province, for limited practice as late as in September

²⁵⁰ Malaysia, The Telemedicine Act 1997 (Act 564).

²⁵¹ Hong Kong, Secretariat, Greater Pearl River Delta Business Council, 2004/05 Annual Report 39, 41 <http://www.info.gov.hk/info/gprd/pdf/gprd_full_report.pdf> accessed 10 March 2012.

2005.²⁵² With the advent of IT and the anticipated trend of future government approvals for relaxing the requirements for clinical practice between Hong Kong and China, either through bilateral recognition of healthcare qualifications or the CEPA, it is projected that the frequent movement of people between the two territories will nourish a faster growth of telemedicine, with a domino effect that more telemedicine applications for exchange of clinical services such as specialty consultations through telecommunications between Hong Kong and China will be made. With this anticipated trend of growth, it is important that legal issues of telemedicine should have been paid sufficient attention by the time when it grows. It is highly undesirable for Hong Kong and China to face similar situations as revealed by a survey in Australia on staff readiness for using emails in mental health services that some respondents would not use emails as a means of communication with patients because of their medico-legal concerns.²⁵³

2.6.2.3 Different Legal Systems

The difference between the respective legal systems in both territories, namely China's civil law system and Hong Kong's common law jurisdiction with the exclusive characteristics of the existence of the Basic Law of Hong Kong under 'One Country Two Systems', may shed new light on the discourse of legal contexts of telemedicine, as there are few studies, if not none, covering legal issues of cross-border practice of telemedicine in Hong Kong and China. Also, not sufficient attention has been paid to the medico-legal system of China in the international academic fields, possibly because of the fact that most literature from China is published in Chinese.

2.6.2.4 First Study on Cross-border Telemedicine between Hong Kong and China

Smith said that there was no systematic research conducted of the medico-legal risks involved in the use of telemedicine.²⁵⁴ This thesis may be the first one to examine the medico-legal liability of practising cross-border telemedicine in Hong Kong and China. With the significant legal difference and the special territorial and

²⁵² See, for example, 'First HK Doctors to Work on Mainland' *China Daily* (Hong Kong Edition, 21 July 2005) <<http://www.china.org.cn/english/China/135682.htm>> accessed 20 December 2011.

²⁵³ Cartwright and others (n 169) 203.

²⁵⁴ Russell G Smith (n 238) 2.

legal relationship, the practice of cross-border telemedicine across the two territories may raise legal issues comparable to those in, say, a federal system like the United States or a political and economic entity like the EU. This research is to study medico-legal issues of practising telemedicine in such a unique legal environment. It is hoped that this study will help fill some of the vacuum in the legal context of provision of telemedicine services across the two territories.

2.7 Research Methodologies

A researcher may in theory make use of a framework such as the SIREN in two approaches: (a) to consider the research question(s) and decide which research methodology may better address them, or (b) to map a particular research method onto the framework to check which areas that method addresses and appraise its relative strength in each element of the framework.²⁵⁵ In practice, only some will be relevant to a particular study, depending on factors such as the study objectives, time and resource constraints, researchers' personal competencies and commitment, and the research methods relevant to the study.²⁵⁶ The choice of any particular research methods to collect qualitative or quantitative data is dependent on 'how best to collect, amass, aggregate, understand, and extract information from the world in any particular situation.'²⁵⁷ The crucial point is that the researcher has to consider the choices consciously with a view to all possibilities, instead of making a decision based on a very limited scope of view.²⁵⁸

Legal research can be broadly classified into doctrinal and non-doctrinal studies. Dobinson and Johns define doctrinal research as '[one] which asks what the law is in a particular area'²⁵⁹ and non-doctrinal research as '[a]ll other legal research [that] can be generally grouped within the categories: problem, policy and law reform based research'²⁶⁰ which often involve social factors and/or social impact of the current law and practice.²⁶¹ These two broad classes of research are not mutually

²⁵⁵ John Mingers, 'Combining IS Research Methods: Towards a Pluralist Methodology' (2001) 12(3) Information Systems Research 240, 251.

²⁵⁶ Ibid.

²⁵⁷ Lee Epstein and Gary King, 'Empirical Research and the Goals of Legal Scholarship: A Reply' (2002) 69(4) The University of Chicago Law Review 191, 201-202.

²⁵⁸ Mingers (n 255) 251.

²⁵⁹ Dobinson and Johns (n 209) 19.

²⁶⁰ Ibid.

²⁶¹ Ibid 20.

exclusive and could be part of a large-scale research project.²⁶² The doctrinal part may be non-empirical in nature and the non-doctrinal may require an empirical qualitative or quantitative study or a combination of both.²⁶³ To summarize, all research methods available to a legal study like the present one include non-empirical and empirical elements.

2.7.1 Non-empirical Study

A legal research on telemedicine will inevitably touch upon international law and some domestic law, as in theory telemedicine may be practised everywhere around the world, as far as telecommunication networks and equipment are available. The international legal system is signified by ‘its decentralised, consensual, and relative primitive character’, which makes international legal research quite different from those involving domestic law, and it is not unusual that views among publicists working in the same field are divergent.²⁶⁴ This character, however, does not hinder the development of international legal research. Article 38(1) of the Statute of the International Court of Justice may provide some practical tips for researchers doing international legal studies, which states that the Court, in deciding international disputes, shall apply general or particular international conventions, international customs, general principles of law recognized by civilized nations, as well as judicial decisions and the teachings of the most highly qualified publicists in various nations to help determine the rules of law.²⁶⁵ To take this article 38(1) into reference, international treaties and customs, general legal principles, judicial decisions, and scholarly published literatures become some basic scopes for an international research.

To follow the approach of article 38(1) of the International Court of Justice, the author has made use of traditional and online searches as the non-empirical research methods to examine medico-legal issues of telemedicine in various countries, in particular the cross-border liability between Hong Kong and China. Traditional methods including library research and literature review are employed to identify international treaties, federal law, national legislation, statutes, subsidiary law, case law, as well as printed materials including books, journal articles, and media reports relevant to this study. References are also made to professional regulations and

²⁶² Ibid.

²⁶³ Ibid.

²⁶⁴ Stephen Hall, ‘Researching International Law’ in McConville and Chui (eds) (n 209) 182.

²⁶⁵ Ibid 182-183.

guidelines as well as official reports of various countries to facilitate the study. However, the traditional approach alone is not sufficient in contemporary legal researches, as '[w]e no longer live in a universe where absolutes can be discovered through judicious reading of common law precedents ... The Internet [has brought] down a second cognitive authority.'²⁶⁶ In parallel with conventional research methods, online study is also conducted by means of electronic legal databases available at the interconnected university libraries of Hong Kong, including but not limited to international legal databases such as Lexis.com and Westlaw for international references, as well as Chinese legal databases such as pkulaw.cn for materials in China. Online research is further enabled through official websites of international and national entities such as the WHO, the UN, and the European Health Telematics Association, and through Internet browsers such as the Google Scholar. The author's personal attendance at professional seminars such as ehealth forums and medical market expositions also serves as a means other than those mentioned above for collection of information and updates. As some literature in China may not be readily available online, the author also went to Chinese cities such as Shenzhen and Guangzhou to locate printed legal texts, cases and materials. Through these research methods, different sources of law are reviewed.

2.7.2 Empirical Study?

An empirical research is based on 'observations of the world' or data as a synonym of facts about the world,²⁶⁷ which may include historical or contemporary information, reviews of legislation or case law, interviews, surveys, primary data collection or secondary archival research.²⁶⁸ In the field of health care, many studies are exploratory in nature and a pilot exploratory survey is required to grasp a sufficient understanding of the problem areas before traditional survey techniques are used to collect data.²⁶⁹ Exploratory surveys are useful tools to explore or try out preliminary concepts about a new issue or deepen the understanding of a topic, no matter whether they are used as an independent research or as the preliminary phase

²⁶⁶ Robert C Berring, 'Legal Information and the Search for Cognitive Authority' (2000) 88(6) California Law Review 1675, 1688 and 1701.

²⁶⁷ Lee Epstein and Gary King, 'Empirical Research and the Goals of Legal Scholarship: The Rules of Inference' (2002) 69(4) The University of Chicago Law Review 1, 2-3.

²⁶⁸ Ibid 3.

²⁶⁹ Andrew H Van de Ven and André L Delbecq, 'The Nominal Group as a Research Instrument for Exploratory Health Studies' (1972) 62(3) American Journal of Public Health 337, 341.

of a descriptive or explanatory study.²⁷⁰ In the present research, as telemedicine is an emerging healthcare service, attempts were made to conduct an empirical study in the form of an exploratory survey. Unfortunately, no findings with significant research values could be presented in this thesis. Details are given in the forthcoming paragraphs.

Use of stakeholder analysis as a survey tool has gained popularity in the fields of management, development, and health policy since the 1990s, as managers, policy makers and researchers have increasingly recognized stakeholders' central roles in influencing the actions and objectives of an organization, a project or a policy direction.²⁷¹ In Europe, van Doosselaere and colleagues classified four groups of actors in telemedicine: (a) citizens and patients, (b) health practitioners and care providers, (c) payers, policy makers and governments, and (d) vendors, suppliers, and commercial partners.²⁷² Correspondingly in Hong Kong, Higa and colleagues identified public hospitals, the Hospital Authority of Hong Kong, the private health care sector, people, and medical staff as the primary stakeholders of the health care system. They deliberately excluded another important stakeholder in the US, namely insurance companies from the list of Hong Kong, owing to the prevalence and the government control of public health care in Hong Kong.²⁷³

To collect the views of stakeholders on the practice of telemedicine in Hong Kong as the first stage of the empirical study, leaving China to the second stage, the author sent a total of 21 questionnaire letters to the organizational stakeholders as identified by Higa et al. and other important local players. The initial use of postal questionnaires was based on the fact that it would consume substantially less resources than data collection through interviews.²⁷⁴ However, the author had not ruled out the chance of interviews and asked the organizational stakeholders if it

²⁷⁰ Alain Pinsonneault and Kenneth L Kraemer, 'Survey Research Methodology in Management Information Systems: An Assessment' (1993) 10(2) *Journal of Management Information Systems* 75, 100.

²⁷¹ Ruairí Brugha and Zsuzsa Varvasovszky, 'Stakeholder analysis: a review' (2000) 15(3) *Health Policy and Planning* 239, 239.

²⁷² Celine van Doosselaere, Jean Herveg, Denise Silber and Petra Wilson, *Legally eHealth – Putting eHealth in its European Legal Context* (The European Commission 2008) 13
<http://ec.europa.eu/information_society/activities/health/docs/studies/legally_ehealth/legally-ehealth-report.pdf> accessed 25 March 2012.

²⁷³ Kunihiro Higa, Bongsik Shin and Grace Au, 'Suggesting a Diffusion Model of Telemedicine – Focus on Hong Kong's Case' (Proceedings of the 30th Hawaii International Conference on System Sciences 1997) 159.

²⁷⁴ Liam Smeeth and Astrid E Fletcher, 'Improving the response rates to questionnaires' (2002) 324(7347) *British Medical Journal* 1168, 1168.

would be possible to interview their responsible officers. The target recipients comprised two government departments,²⁷⁵ the Hospital Authority of Hong Kong (the major public health provider), all twelve private hospitals,²⁷⁶ the Medical Council of Hong Kong (the sole regulatory entity for medical professionals), three universities practising telemedicine and/or having faculties of medicine,²⁷⁷ and two professional associations.²⁷⁸ Letters were not sent to individual public hospitals as they were under the management of the Hospital Authority. General citizens and patients in the context of ‘people’ and medical staff as classified by Higa et al. as stakeholders were not included in the target populations of the empirical study because of resource constraints.

The first batch of letters was posted to the stakeholders mentioned above at the end of 2007, enquiring about how they perceived legal issues of telemedicine and what their concerns would be. Consent of the relevant stakeholders was also sought for the release of information such as internal policy, guidelines, and protocols of telemedicine practices (both legal and non-legal), as well as information and statistics on their telemedicine practices. Alternatively, their approvals were applied for the author’s access to information and documents under their control and/or interviewing their colleagues responsible for telemedicine. Reminders were issued in April 2008 as follow-ups. A sample of the first survey letters and the reminders is enclosed in the Appendix. Regrettably, there was either no reply or no positive feedback received. McConville said, ‘official institutions have great power to influence the production of knowledge by placing constraints on what can be done ... for example, denying researchers access ...’²⁷⁹ Out of the 21 targeted recipients, 11 did not give any responses. 10 of them sent in their replies and among which, 5 private hospitals and the Faculty of Medicine of the University of Hong Kong said that they could not help this research. The Hospital Authority and the Department of Health attached

²⁷⁵ Including Food and Health Bureau and Department of Health of Hong Kong.

²⁷⁶ Including The Canossa Hospital (Caritas), The Hong Kong Central Hospital, The Evangel Hospital, The Matilda International Hospital, The Precious Blood Hospital (Caritas), The Hong Kong Adventist Hospital, The Tsuen Wan Adventist Hospital, The Hong Kong Baptist Hospital, St Paul’s Hospital, St Teresa’s Hospital, The Union Hospital, and The Hong Kong Sanatorium & Hospital.

²⁷⁷ Comprising The Telemedicine Centre of the Chinese University of Hong Kong, The Tele-rehabilitation Centre of the Hong Kong Polytechnic University, and The Faculty of Medicine of the University of Hong Kong.

²⁷⁸ The recipients were The Hong Kong Telemedicine Association and The Hong Kong Private Hospitals Association.

²⁷⁹ Mike McConville, ‘Development of Empirical Techniques and Theory’ in McConville and Chui (eds) (n 209) 213.

indirectly relevant information. The Medical Council reiterated its statutory duties in Hong Kong and had nothing to say about telemedicine. The Food and Health Bureau only gave an acknowledgement of receipt of the research letter.

The level of response rate is a crucial factor in determining the value of survey findings,²⁸⁰ as poor response rate will introduce uncertainty²⁸¹ and undermine the validity of the findings,²⁸² and may further threaten the validity of inferences. The author faced a research dilemma, if not difficulty, at that moment. Phophalia said that a research manager may undergo the following decision making process in order to solve problems in research: (a) To recognize a situation where a decision has to be made as to what the next action will be, (b) to identify and develop alternative courses of action, (c) to evaluate the alternatives, (d) to choose one of the alternatives, and (e) to implement the chosen alternative action.²⁸³ In view of the results of the aforesaid qualitative research conducted in Hong Kong, the practical and technical difficulties arising when the author was physically in London in 2009/10 while doing this research, as well as the resource and time constraints, the author made a difficult decision that no further empirical study would be carried out, both in Hong Kong and China. Instead, the use of other research methodologies mentioned above would be continued to follow up legal developments in the two territories in relation to telemedicine.

2.8 Limitations of this Study

Telemedicine is a practice involving a wide coverage of multi-disciplines of law, for example, tort, contract, cyber law, and criminal laws, etc. It is also a practice running across multi-disciplines of professionals including legal practitioners, medical experts and IT specialists. Owing to limitations of resources, length, and time, the current research can only cover some legal areas of the discourse and a few jurisdictions across the globe. Other legal issues of telemedicine such as funding, reimbursement and taxation are not detailed in this study. Another limitation is that telemedicine is still a developing topic. Case law on clinical negligence of

²⁸⁰ Yehuda Baruch and Brooks C Holtom, 'Survey response rate levels and trends in organizational research' (2008) 61(8) Human Relations 1139, 1140.

²⁸¹ Smeeth and Fletcher (n 274) 1168.

²⁸² Claire Snowdon, Jo Garcia and Diana Elbourne, 'Reactions of participants to the results of a randomised controlled trial: exploratory study' (1998) 317(7150) British Medical Journal 21, 21.

²⁸³ A K Phophalia, *Modern research methodology: new trends and techniques* (Paradise Publishers, Jaipur, India 2010) 142.

telemedicine worldwide is extremely rare if not none. There is currently no legislation enacted in Hong Kong and China. Availability of local legal and non-clinical reference materials in relation to medico-legal liability is limited. Not only is the amount of literature in relation to medico-legal liability of telemedicine scarce in Hong Kong and China, the same is true in other cities and countries. The EC found that the legal literature about telemedicine in Belgium was only confined to personal data protection,²⁸⁴ but the legal scope of telemedicine is more than that. Any reference and discussion in this thesis made against this background can only be treated as the best ‘guesstimate’ as at the time of writing. A further limitation added to the above is the insufficient availability of English materials in the legal context of clinical negligence and telemedicine in China, which makes translation necessary occasionally. This has caused a technical difficulty to some extent especially in translating Chinese legal concepts and terminologies. Last but not least, there is a technical limitation. The author has tried his best to provide the most current and accurate information such as website addresses, but some may have changed after his submission of this thesis to the City University of Hong Kong in 2012.

²⁸⁴ European Commission, Directorate General Information Society (2009) (n 163) 98.

CHAPTER 3

Clinical Negligence and Telemedicine

‘Telemedicine is probably not an adequate legal concept because it covers a much too heterogeneous field. Legal issues can better be tackled by approaching the various situations covered by this concept from another point of view.’

— European Commission²⁸⁵

3.1 Chapter Summary

The impact of clinical negligence on a society is enormous. Although telemedicine is a state-of-the-art medical technology, it does not escape the risks of clinical negligence. At common law, telemedicine complicates traditional clinical negligence claims in at least three aspects: the health practitioner-patient relationship, the duty of care and the standard of care.²⁸⁶ How civil law systems may treat telemedicine is not widely studied or published. This chapter gives a brief introduction to the legal considerations of the traditional common law tort system which may be applicable to clinical negligence claims in the practice of telemedicine and explores a few civil law systems in the same context.

3.2 Clinical Negligence

3.2.1 A Snapshot of the Impact of Clinical Negligence in a Society

Clinical negligence incurs enormous human and financial costs.²⁸⁷ As far as human costs are concerned, Fenn and colleagues found that in the UK, 4.8% of 8,206 English respondents had suffered some injuries or impairments caused by their medical treatment or care in the previous three years, of which about 30% claimed that the injuries were permanent in nature, and 35% who had worked at the time of injury had to take a minimum of one year’s leave, retire, or handle light duties.²⁸⁸ Pleasence and colleagues surveyed that 56% and 25.2% of 5,015 respondents in England and Wales who reported clinical negligence problems had respectively

²⁸⁵ European Commission, Directorate General Information Society (2009) (n 163) 128.

²⁸⁶ Kuszler (n 5) 307.

²⁸⁷ United Kingdom, National Audit Office Press Office, ‘Press Release – Handling Clinical Negligence Claims in England’ (3 May 2001)

<http://www.nao.org.uk/whats_new/0001/0001403.aspx> accessed 13 February 2012.

²⁸⁸ Fenn, Gray and Rickman (2004a) (n 231) F285.

suffered from physical and stress illnesses.²⁸⁹ In the US, a recent study revealed that in the period of 2007-2009, there were 708,642 total patient safety events which resulted in 79,670 potentially preventable patient deaths.²⁹⁰ Doctors also suffer from medical lawsuits. Poythress and Brodsky pointed out that chronic involvements of doctors in medical litigation processes often result in psychological symptoms like depression and pervasive anger.²⁹¹

Clinical negligence has also put a heavy burden on healthcare expenditures. For instance, the fear of litigation may lead to doctors' practice of defensive medicine,²⁹² which in turn increases healthcare expenses, as doctors may exercise their 'liability-induced discretion' to order frequently costly diagnostic tests for patients without apparently lowering the readmission rate.²⁹³ In the UK, the Medical Defence Union paid £78 million in compensation in 2000²⁹⁴ and projected that the costs of medical claims were increasing by approximately 13-15% annually, rising from £5.4 million in 1995 to £23.3 million in 2004.²⁹⁵ In Australia, adverse events in hospitals including those that were non-preventable have cost AUD1.7²⁹⁶-2 billion²⁹⁷ a year. In China, hospital expenditure in compensation for medical events has been

²⁸⁹ Pascoe Pleasence, Nigel J Balmer, Alexy Buck, Marisol Smith, and Ash Patel, 'Mounting Problems: Further Evidence of the Social, Economic and Health Consequences of Civil Justice Problems' in Pascoe Pleasence, Alexy Buck, and Nigel J Balmer (eds), *Transforming Lives: Law and Social Process* (The Stationery Office, UK 2007) 71-73.

²⁹⁰ Kristin Reed and Rick May, *HealthGrades Patient Safety in American Hospitals Study* (HealthGrades, Colorado, United States 2011) 1.

²⁹¹ Norman G Poythress and Stanley L Brodsky, 'In the Wake of a Negligent Release Law Suit' (1992) 16(2) *Law and Human Behavior* 155, 157.

²⁹² Stanley L Brodsky, 'Fear of Litigation in Mental Health Professionals' (1988) 15(4) *Criminal Justice and Behavior* 492, 497.

²⁹³ Paul Fenn, Alastair Gray and Neil Rickman, 'Enterprise liability, insurance and defensive medicine: UK evidence (March 2004)' (2004b) 1 <<http://www.bristol.ac.uk/cmpo/events/seminar/fenn.pdf>> accessed 16 March 2011.

²⁹⁴ Medical Defence Union, 'MDU paid £78 million in compensation in 2000' (5 August 2001) <http://www.the-mdu.com/Search/hidden_Article.asp?articleID=302&contentType=Media+release&articleTitle=MDU+paid+%A378million+in+compensation+in+2000&userType=>> accessed 13 February 2012.

²⁹⁵ Medical Defence Union, 'Increase in million pound compensation awards against doctors' (14 March 2005) <http://www.the-mdu.com/Search/hidden_Article.asp?articleID=1269&contentType=Media%20release&articleTitle=Increase+in+million+pound+compensation+awards+against+doctors&userType=>> accessed 13 February 2012.

²⁹⁶ Rigby and colleagues, 1999; as cited in Matthew Jackson, 'Government, medical error, and problem definition' in Simon Barraclough and Heather Gardner (eds), *Analysing health policy: A problem oriented approach* (Elsevier, Marrickville, Australia 2008) 190.

²⁹⁷ Ehsani and others, 2006; as cited in Matthew Jackson (n 296) 190.

over RMB4.2 billion a year.²⁹⁸ In Japan, following the change of its non-litigious culture, the civil litigation rate in general increased by 24% from 1986 to 2001,²⁹⁹ and the budget of the Japanese Ministry of Health, Labor, and Welfare for indemnity payments and defence costs also increased about 18 times in 10 years from US\$348,200 in 1989 to US\$6.3 million in 1999.³⁰⁰

The public holds governments accountable for any medical events and expects them to investigate and fix the problems. Governments of different countries have employed a series of measures such as legislation, licensing, policy directives, approval procedures, inspections and guidelines to manage medical risks and regulate the safety and quality of conventional healthcare services.³⁰¹ In the US, for instance, emergency enactment of legislation was used in the mid 1970s as a means by various state governments to tackle the ‘malpractice crisis’ and slow down the rising healthcare expenditure incurred in medical liability cases.³⁰² The need for further medical malpractice reform has become nearly a universal agreement³⁰³ since then. However, these measures are not foolproof and the American Medical Association still classified 22 states of the US as being in ‘medical liability crises’.³⁰⁴ Debates continue in recent decades in the US on the nature of medical liability and how to reform it³⁰⁵ and studies are carried out from different perspectives like a comparison of the behaviours of lay jurors and legal professionals in the award of noneconomic damages such as pain and suffering in medical negligence cases.³⁰⁶ In the UK, the English tort system has been mostly criticized in clinical negligence litigation.³⁰⁷ In

²⁹⁸ Lian Yang and Ying Li, ‘Legal Considerations on the Determination of Medical Events’ (2010) 200 Business China 146 (楊煉及李瑛, ‘醫療事故認定的法律思考’ (2010) 200 中國商界 146; *yang liàn jī lǐ yīng*, ‘yī liáo shì gù rèn dìng de fǎ lǜ sī kǎo’ *zhōng guó shāng jiè* 146), 146.

²⁹⁹ Tom Ginsburg and Glenn Hoetker, ‘The Unreluctant Litigant? An Empirical Analysis of Japan’s Turn to Litigation’ (University of Illinois Legal Working Paper Series, University of Illinois Law and Economics Working Papers, Working Paper 14, September 2004) 26.

³⁰⁰ Kazue Nakajima, Catherine Keyes, Tatsuo Kuroyanagi and Kozo Tatara, ‘Medical Malpractice and Legal Resolution Systems in Japan’ (2001) 285(12) *Journal of American Medical Association* 1632, 1638.

³⁰¹ Matthew Jackson (n 296) 193.

³⁰² Byron H Demorest, ‘Important Medicolegal Legislation’ (1980) 20(4) *International Ophthalmology Clinics* 21, 21.

³⁰³ M J White, ‘The value of liability in medical malpractice’ (1994) 13(4) *Health Affairs* 75, 75.

³⁰⁴ Kyle Miller, ‘Putting the Caps on Caps: Reconciling the Goal of Medical Malpractice Reform with the Twin Objectives of Tort Law’ (2006) 59(4) *Vanderbilt Law Review* 1457, 1462.

³⁰⁵ See, for example, Catherine T Struve, ‘Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation’ (2003-2004) 72(4) *Fordham Law Review* 943.

³⁰⁶ Neil Vidmar and Jeffrey J Rice, ‘Assessments of Noneconomic Damage Awards in Medical Negligence: A Comparison of Jurors with Legal Professionals’ (1993) 78(4) *Iowa Law Review* 883.

³⁰⁷ Jo Roll, ‘Research Paper 06/29: The NHS Redress Bill [HL] (Bill 137 of 2005/6)’ 13 (Social Policy Section, House of Commons Library, London, United Kingdom 2006).

his report entitled *Access to Justice*, which led to the reform of the English civil litigation system and has put in place a new set of civil procedure rules applying to all civil lawsuits including clinical negligence cases, Lord Woolf said, '[I]t was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants ...'.³⁰⁸ Samuels echoed that the English tort system for medical mishap was 'costly, administratively inefficient, beset by delay, and the costs often exceed[ed] the compensation and comparatively few patients end[ed] up with compensation ...'.³⁰⁹ In Canada, Prichard issued his report on liability and compensation in health care³¹⁰ in 1990 with a view to a perceived 'malpractice crisis' in the late 1980s and recommended an alternative compensation system for people suffering avoidable injuries in alleged medical events, while maintaining their right to proceed with legal claims in tort,³¹¹ as the tortious litigation system still poses 'a threat' in a positive way to health practitioners in Canada to reduce the frequency of avoidable injuries arising from clinical negligence.³¹² In Australia, there was a perceived litigation crisis as well when the biggest medical defence organization went into voluntary liquidation in 2002. Mass media reports together with other political considerations such as the lobbying by the Australian Medical Association made the Commonwealth and state governments of Australia introduce significant changes in the law in areas of both medical negligence and personal injury litigation.³¹³

Although other studies showed that the tortious clinical negligence system may provide a strong financial incentive to deter doctors and hospitals from provision of substandard care,³¹⁴ different reforms to the traditional common law of tort were studied in countries including Australia, Canada, the UK and the US to address its shortcomings such as high costs of litigation and defensive medicine. Some

³⁰⁸ Harry Kenneth Woolf, 'Access to Justice: The Final Report' (Her Majesty's Stationery Office, London 1996) Chapter 15 [2] <<http://www.dca.gov.uk/civil/final/contents.htm>> accessed 13 February 2012.

³⁰⁹ Alec Samuels, 'The English Tort System for Medical Mishaps' (2004) 72(4) *Medico-Legal Journal* 147 [2].

³¹⁰ J R S Prichard, *Liability and Compensation in Health Care. A Report to the Conference of Deputy Ministers of Health and Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care* (University of Toronto Press, Canada 1990).

³¹¹ Joan M Gilmour, *Patient Safety, Medical Error and Tort Law: An International Comparison – Final Report* (HPRP Project Number 6795-15-203/5760003, Health Canada, 2006) 21-22.

³¹² Patrick Sullivan, 'Changes needed if liability crisis to be averted, Prichard report says' (1990) 143(9) *Canadian Medical Association Journal* 941, 941.

³¹³ Fiona Tito Wheatland, 'Medical Indemnity Reform in Australia: "First Do No Harm"' (2005) 33(3) *The Journal of Law, Medicine & Ethics* 429.

³¹⁴ M J White (n 303) 86.

important directions have been identified, including but not limited to reform of the conventional tort system such as capping damages, reform to the standard of care through case law or written clinical practice guidelines complying with which health practitioners and institutes would not be presumed to be negligent, imposing restrictions on lawyers' contingent and conditional fees to eliminate weak claims, and other alternative compensation mechanisms such as an alternative dispute resolution system and a no-fault system.³¹⁵ In Canada, for example, reforms to the civil justice system in various provinces focused only on measures to reduce the costs of judgments and accessing the justice system, rather than clinical negligence litigation.³¹⁶ In other countries, a more radical approach was adopted. In particular, no-fault schemes have been set up in some countries such as Denmark,³¹⁷ Sweden, and New Zealand,³¹⁸ in contrast to the traditional tort system. For instance, the New Zealand Accident Compensation Scheme established under the Accident Compensation Act 1972 of New Zealand covers 'compensation which is obtainable without proving fault and is provided outside the tort system'.³¹⁹

3.3 Legal Considerations on Clinical Negligence Claims

Although clinical negligence claims are conventionally considered a legal arena encountering problems of causation and remoteness,³²⁰ in order to sustain the growth of telemedicine and properly handle the risks associated with ehealth applications, from a practical point of view, health practitioners have to understand the legal elements constituting medical malpractice in practising telemedicine.

3.3.1 The Common Law System in the UK

In the UK, Alderson B in *Blyth v The Company of Proprietors of the Birmingham Waterworks* said, 'Negligence is the omission to do something which a

³¹⁵ Kessler, Summerton and Graham (n 228) 242-245.

³¹⁶ Gilmour (2006) (n 311) 22.

³¹⁷ Ann Ulrich, 'An Evaluation of the Danish No-Fault System for Compensating Medical Injuries' (1994) 3 *Annals of Health Law* 243.

³¹⁸ Allen B Kachalia, Michelle M Mello, Troyen A Brennan and David M Studdert, 'Beyond negligence: Avoidability and medical injury compensation' (2008) 66(2) *Social Science & Medicine* 387.

³¹⁹ James C Johnston, 'Tort Reform System: Medical Negligence in New Zealand' in American College of Legal Medicine, *Medical Malpractice Survival Handbook 2007* (Mosby/Elsevier Publisher, Philadelphia, PA 2006) 287-288.

³²⁰ Christopher Walton, Roger Cooper, Simon E Wood, and Stephen Todd (eds), *Charlesworth & Percy on Negligence* (12th edn, Sweet & Maxwell 2010) 426 [6-54] and 614 [9-143].

reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.’³²¹ Early English common law did not concern the concept of negligence but focused on procedural remedies.³²² The basis of the modern English negligence law is *Donoghue v Stevenson*.³²³ Following the decades’ judicial development since *Donoghue*, it is quite clear that in order to succeed in a claim of clinical negligence in the UK, patients or other claimants such as a patient’s children, spouse or parents³²⁴ have to prove the following:³²⁵

- (a) The defendant health practitioner owed the claimant a duty of care;
- (b) the defendant failed to exercise reasonable care which resulted in a breach of that duty;
- (c) the claimant suffered from injuries caused by the defendant’s breach of duty; and
- (d) the injuries were not too remote.

3.3.1.1 Applications of the English Legal Considerations of Clinical Negligence in Other Common Law Countries

The above elements of English tort law for clinical negligence claims are relatively uniformly applied across different common law countries. In the US, while clinical negligence is considered ‘a distinct branch of tort law’,³²⁶ case precedents applying the state laws of, for instance, Puerto Rico,³²⁷ Louisiana,³²⁸ Connecticut,³²⁹ Pennsylvania,³³⁰ Maryland,³³¹ New York,³³² Texas,³³³ and California,³³⁴ etc. have

³²¹ (1856) 11 Exch Reports (Welsby, Hurlstone and Gordon) 781, 784, 156 ER 1047, 1049 (Court of Exchequer).

³²² Fleming James, ‘Scope of Duty in Negligence Cases’ (1952) 47(6) Northwestern University Law Review 778, 779.

³²³ [1932] AC 562, 1932 SC (HL) 31 (House of Lords).

³²⁴ Goh Lee Gan, ‘Medical Responsibility and Third Parties’ in Yeo Khee Quan, Leslie Chew, Goh Lee Gan, Terry Kaan, Kuah Boon Theng, and Edwin Tong, *Essentials of Medical Law* (Sweet & Maxwell Asia 2004) 251-252.

³²⁵ Emily Jackson, *Medical Law – Text, Cases and Materials* (Oxford University Press 2006) 108.

³²⁶ Philip G Peters, ‘Health Care Law Breaking Down the Boundaries of Malpractice Law’ (2000) 65(4) Missouri Law Review 1047, 1051.

³²⁷ *Rolon-Alvarado v Municipality of San Juan*, 1 F.3d 74, 77 (C.A.1 (Puerto Rico), 1993) (United States Court of Appeals, First Circuit).

³²⁸ *Mills v Levy* 537 F.2d 1331, 1332 (C.A.La. 1976) (United States Court of Appeals, Fifth Circuit).

³²⁹ *Powers v United States* 589 F. Supp. 1084, 1099 (D.C.Conn., 1984) (District Court for Connecticut).

³³⁰ *MacDonald v United States* 767 F. Supp. 1295, 1307 (M.D.Pa., 1991) (District Court for Pennsylvania).

³³¹ *Macguineas v United States* 738 F. Supp. 566, 569 (D.D.C., 1990) (District Court for Columbia).

shown that the elements of a cause of action for alleged clinical negligence cases are comparable across jurisdictions in the US.³³⁵

In Canada, the Supreme Court has not only once approved Meredith's four conditions of negligence, namely, a doctor's legal duty of care, the doctor's breach of that duty, patient's loss or injury, and the loss or injury as a direct result of the doctor's negligence, and ruled that the success of a medical claim founded on clinical negligence should be subject to the existence of these four conditions.³³⁶ For instance, the respondent in *Videto v Kennedy* claimed that the appellant had breached his duty of care to fully disclose the risks involved in the operation and brought a malpractice action against the defendant on the ground of lack of informed consent. The Ontario Court of Appeal held that for the respondent to succeed there must be both a breach of the appellant's duty of disclosure and such breach must have caused the respondent's damages.³³⁷

In Australia, the legal elements of English tort law were also applied in, for example, *Rogers v Whitaker*³³⁸ by the High Court (the ultimate court of appeal), although in the 'Ipp Report',³³⁹ Ipp and other panel members in the process of reviewing the effectiveness and operation of common law negligence principles to limit liability arising from personal injury or death³⁴⁰ recommended in 2002 a series of changes, such as the introduction of a statutory test to determine the standard of care of a medical practitioner.³⁴¹ After the publication of the Ipp Report, various states of Australia quickly enacted their civil liability statutes.³⁴² The Ipp Report did modify some aspects of the common law in Australia in this regard. For instance,

³³² *Arkin v Gittleson* 32 F.3d 658, 664 (C.A.2 (N.Y.), 1994) (United States Court of Appeals, Second Circuit).

³³³ *Hollis v United States* 323 F.3d 330, 336 (C.A.5 (Tex.), 2003) (United States Court of Appeals, Fifth Circuit).

³³⁴ *Willard v Hagemeister* 121 Cal.App.3d 406, 412, 175 Cal.Rptr. 365 (Cal.App.2.Dist. 1981) (Court of Appeal of California, Second District).

³³⁵ Fleisher and Datta (n 27) 1-47 §1.04[3].

³³⁶ See, for instance, *Young v St. Rita Hospital* (1986), 75 NSR (2d) 239, 186 APR 239 (Nova Scotia Trial Division); *Anderson v Grace Maternity Hospital* (1989), 93 NSR (2d) 141, 242 APR 141 (Supreme Court of Nova Scotia).

³³⁷ (1981), 17 CCLT 307, 33 OR (2d) 497, 125 DLR (3d) 127 (Ontario Court of Appeal), [9] (Howland CJO).

³³⁸ [1992] HCA 58, (1992) 175 CLR 479, 67 ALJR 47, 109 ALR 625, [1993] 4 Medical Law Reports 79 (High Court of Australia).

³³⁹ David Andrew Ipp, Peter Cane, Don Sheldon and Ian Macintosh, *Review of the Law of Negligence Final Report* (Australia 2002).

³⁴⁰ *Ibid* ix.

³⁴¹ *Ibid* 1, Recommendation 3.

³⁴² Michael McHugh, 'Introduction: Sydney Law Review Torts Special Issue' (2005) 27(3) Sydney Law Review 385, 385.

many of the provisions in the Civil Liability Amendment (Personal Responsibility) Bill of New South Wales followed ‘the original exposure draft on those recommendations’ in the Ipp Report.³⁴³

3.3.1.2 Applications in Hong Kong

Prior to the sovereignty change from the British colonial administration to China on 1 July 1997, Hong Kong inherited from the UK a common law system ‘very similar to that of its colonial masters’.³⁴⁴ At that time, Hong Kong relied heavily on case law from the UK. In addition to the English case law, Hong Kong also made reference to legal authorities from other jurisdictions such as Canada, the US, and the European Court of Human Rights in interpreting some particular issues like the Hong Kong Bill of Rights Ordinance 1991.³⁴⁵

To maintain the political and economic stability of Hong Kong after the sovereignty change, it has been stipulated in the Basic Law or the ‘mini-constitution’ of Hong Kong that the laws previously in force in Hong Kong, i.e. the common law, rules of equity, ordinances, subordinate legislation and customary law are to be maintained, except for those contravening the Basic Law, and subject to any legislative amendments by the Legislative Council of Hong Kong.³⁴⁶ With regard to the doctrine of *stare decisis*, the Court of Final Appeal in *Bank of East Asia Ltd v Tsien Wui Marble Factory Ltd & Others*³⁴⁷ said that in accordance with articles 8 and 18 of the Basic Law, part of the common law maintained in Hong Kong must be the common law of England as applied to Hong Kong immediately before the changeover on 1 July 1997. Although decisions of the House of Lords in the UK would no longer bind the courts in Hong Kong, it was thought that decisions of the Hong Kong courts would not depart from the English law applied immediately before 1 July 1997 without good reason. In *A Solicitor (24/07) v Law Society of Hong*

³⁴³ Australia, New South Wales, *Civil Liability Amendment (Personal Responsibility) Bill – Second Reading* (NSW Hansard Articles: LA: 23/10/2002: #12) (2002), 5764
<[http://www.parliament.nsw.gov.au/prod/parlament/nswbills.nsf/0/eede6d8b4bb7742aca256c5b0016bfd/\\$FILE/A9202.pdf](http://www.parliament.nsw.gov.au/prod/parlament/nswbills.nsf/0/eede6d8b4bb7742aca256c5b0016bfd/$FILE/A9202.pdf)> accessed 5 October 2012.

³⁴⁴ Ian Dobinson and Derek Roebuck, *Introduction to Law in the Hong Kong SAR* (2nd edn, Sweet & Maxwell Asia, Hong Kong 1998) 1.

³⁴⁵ Joseph Y S Cheng and Paul C K Kwong (eds), *The Other Hong Kong Report 1992* (The Chinese University Press, Hong Kong 1992) 16.

³⁴⁶ Hong Kong, The Basic Law of the Hong Kong Special Administrative Region of the People’s Republic of China, art 8.

³⁴⁷ (1999) 2 HKCFAR 349, 353, [2000] 1 HKLRD 268, 272 (Court of Final Appeal) (Nazareth NPJ).

Kong,³⁴⁸ the Court of Final Appeal has further elaborated that the common law prior to the changeover continues to apply in Hong Kong after the resumption of Chinese sovereignty. In particular, the decisions of the Privy Council of the UK on appeal from Hong Kong before 1 July 1997 remain binding on the Court of Appeal and lower courts, whilst those on appeal from other jurisdictions follow the pre-1997 standing that they had never been binding in Hong Kong, and the rulings of the House of Lords of the UK from other jurisdictions were persuasive but not binding. In the area of tort, the Court of Final Appeal in *Yu Yu Kai v Chan Chi Keung*³⁴⁹ also endorsed the English approach. In other words, in the area of clinical negligence, Hong Kong continues the common law tort and may not deviate much from the English legal considerations. For example, before the changeover of sovereignty, the Court of Appeal in *Attorney General v Ho Hing Mui*³⁵⁰ referred to the *Bolam*³⁵¹ principle, and after the changeover, the Court of Appeal in a recent case alleging a doctor's professional misconduct, *Dr Leung Shu Piu v The Medical Council of Hong Kong*,³⁵² still referred to the same principle.

3.3.2 The Civil Law System

Unlike the common law system, civil law jurisdictions use systematically codified legislations as the main source of the law, and courts are not bound to follow previous judicial decisions.³⁵³ Medical laws of a few jurisdictions are briefed below.

3.3.2.1 China

3.3.2.1.1 A Brief on the Chinese Law

Before the enactment of the Tort Law of the People's Republic of China³⁵⁴ ('the Chinese Tort Law 2010'), which was promulgated in 2009 and came into effect in July 2010, the government of China and its health administrative agencies were the

³⁴⁸ (2008) 11 HKCFAR 117, [2008] 2 HKLRD 576 (Court of Final Appeal).

³⁴⁹ (2009) 12 HKCFAR 705, [2009] HKEC 328 (Court of Final Appeal).

³⁵⁰ [1982] HKC 424, CACV000061/1982 (Court of Appeal).

³⁵¹ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

³⁵² [2011] HKEC 348 (Court of Appeal).

³⁵³ Joseph Dainow, 'The Civil Law and the Common Law: Some Points of Comparison' (1966-1967) 15(3) The American Journal of Comparative Law 419, 424.

³⁵⁴ Tort Law of the People's Republic of China (中華人民共和國侵權責任法; *zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ*) 2010.

only entities³⁵⁵ responsible for making and enforcing medical negligence laws through the old Measures for the Handling of Medical Accidents 1987.³⁵⁶ In 2002, the Chinese government passed the Regulation on the Handling of Medical Accidents³⁵⁷ ('the Chinese HMA Regulation 2002') to replace the previous set of regulations enacted in 1987 to govern the liability of any 'medical accident'.³⁵⁸ Article 2 of the Chinese HMA Regulation 2002 defines a 'medical accident' as one that has caused personal injury to a patient negligently by a medical institution or the staff thereof in the activities of medical treatment which have violated 'the laws, regulations, ministerial rules concerning medical treatment and health, or the standards or conventions of medical treatment and nursing'.³⁵⁹

A 'medical accident' is a special occupational event in China and the following conditions has to be met before an event becomes a medical incident:³⁶⁰

- (a) The incident has to occur during a clinical activity;
- (b) 'The subject of legal liability'³⁶¹ is a medical institute registered with a Chinese practising licence or a licensed health practitioner. It is worth noting that non-medical staff of a medical institute such as staff of a hospital laundry, canteen and vehicular fleet who has caused personal injury to a patient owing to inappropriate behaviour(s) may also commit a medical accident;
- (c) Existence of a medical error in the clinical activity which has violated the laws, regulations, ministerial rules concerning medical treatment and health, or the standards or conventions of medical treatment and nursing. The error here involves action and inaction. Action means those prohibited under the laws, regulations and commonly recognized conventions such as performing surgery

³⁵⁵ Chao Xi and Lixin Yang, 'Medical liability laws in China: The tale of two regimes' (2011) 19 Tort Law Review 65, 65.

³⁵⁶ '醫療事故處理辦法' (*yī liáo shì gù chǔ lǐ bàn fǎ*) in Chinese.

³⁵⁷ China, Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002.

³⁵⁸ '醫療事故' (*yī liáo shì gù*) in Chinese.

³⁵⁹ '醫療衛生管理法律、行政法規、部門規章和診療護理規範、常規' (*yī liáo wèi shēng guǎn lǐ fǎ lǜ, xíng zhèng fǎ guī, bù mén guī zhāng hé zhěn liáo hù lǐ guī fàn, cháng guī*) in Chinese.

³⁶⁰ Mao-Sheng Zhao and Jing Zhang, *Introduction to Medicine and Law* (3rd edn, China Logistics Publishing House, Beijing 2011) (趙卯生及張晶(編著), 醫學法學概論(第三版, 中國物資出版社, 中國北京 2011); *zhào mǎo shēng jí zhāng jīng (biān zhù), yī xué fǎ xué gài lùn (dì sān bǎn), zhōng guó wù zī chū bǎn shè, zhōng guó bēi jīng* 2011)) 73-74.

³⁶¹ '法律責任主體' (*fǎ lǜ zé rèn zhǔ tǐ*) in Chinese.

without the support of medical evidence³⁶² or an invasive investigation which has caused an unfavourable consequence. Inaction refers to the situation where a medical institute or a health practitioner has not carried out an appropriate action which has been promulgated in the job responsibility of a particular position or commonly recognized conventions, or has not carried it out in a serious manner, such as refusal to treat a seriously ill patient or unapproved absence from duty causing an unfavourable consequence to a patient. To decide whether an event is a medical accident, it depends on two factors: (i) the legality of an action or inaction, i.e. whether it has violated the relevant health and medical laws and regulations, and (ii) whether there is actual damage to a patient;

- (d) The damage caused has to meet regulatory standards stipulated in the laws and regulations; and
- (e) Causation has to be established between the damage and the action or inaction. If there are multiple possible causes, each cause has to be examined in a proper manner to avoid bias. Examination of the causes is also required to see if the damage will be caused unavoidably because of a patient's personal health condition, irrespective of whether a medical institute and/or a health practitioner has taken an action or inaction.

Unfavourable consequences arising from the following circumstances will not be deemed a medical accident:³⁶³ (a) emergency rescues, (b) patients' unusual state of illness or personal special physique, (c) unpredictable or not preventable events under the existing technical and medical conditions, (d) infections as result of fault free blood transfusions, (e) patients' own delay in medical treatment, and (f) force majeure.

Following the enactment of the Chinese Tort Law 2010, there exist two 'medical liability regimes': an administrative regime and a judicial regime.³⁶⁴ The administrative regime runs the Chinese HMA Regulation 2002 and the judicial

³⁶² '無指征手術' (*wú zhǐ zhēng shǒu shù*) in Chinese.

³⁶³ China, Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 33.

³⁶⁴ Xi and Yang (n 355) 65-66.

regime runs the Chinese Tort Law 2010 to deal with non-medical-accident negligence or ‘medical fault’ as it is commonly known.³⁶⁵ A patient may now initiate a claim based on ‘medical fault’ under the Chinese Tort Law 2010, as opposed to ‘medical accident’ under the Chinese HMA Regulation 2002. In medical-fault claims, the court will also be assisted by expert opinions to determine negligence and causation. The Chinese Tort Law 2010 also allows a deceased patient’s estate to claim for damages arising from death caused by medical negligence, which are not allowed under the Chinese HMA Regulations 2002.³⁶⁶

3.3.2.1.2 Award of Damages

In accordance with the Chinese HMA Regulation 2002, medical accidents in China are classified into four grades in accordance with the seriousness of patient injury, ranging from the most serious grade involving death or serious disability to the least serious one causing ‘obvious injury to the body of patients or other consequences’.³⁶⁷ In brief, the following three factors will be taken into account to determine the value of damages: (a) the grade of injury in a medical accident, (b) the seriousness of the medical negligent act causing the injury, and (c) the relationship between the injury caused by the medical accident and the patient’s original illness.³⁶⁸ Detailed calculation methods of a medical accident and the punishment provisions for medical institutes, clinical staff and experts involved in the technical authentication are stated respectively in articles 49-52 and 53-59 of the Chinese HMA Regulation 2002. In addition to the award of damages, the administrative departments of health may also follow the current laws, regulations and ministerial rules to give ‘administrative punishments’ to the medical institutions and staff concerned.³⁶⁹ The lower courts in China are required to report in a timely manner to the Supreme People’s Court level by level major issues other than compensation identified during the trials of civil cases involving medical malpractices.³⁷⁰

³⁶⁵ Ibid 68.

³⁶⁶ Ibid 68-70.

³⁶⁷ China, Regulation on the Handling of Medical Accidents of People’s Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 4.

³⁶⁸ Ibid art 49.

³⁶⁹ Ibid art 35.

³⁷⁰ China, Notice of the Supreme People’s Court on Trying Civil Cases on Medical Disputes by Referring to the ‘Regulation on Handling Medical Malpractices (*sic*)’ (6 January 2003) (最高人民法院關於參照‘醫療事故處理條例’審理醫療糾紛民事案件的通知 (2003 年 1 月 6 日); *zuì gāo rén*

3.3.2.2 Other Civil Law Countries

In Germany,³⁷¹ there is no legislation to govern medical liability. Rather, the German courts have developed special rules on the issue of medical liability. Contractual liability and tortious liability co-exist with each other. A contract for health services exists between a health practitioner and a patient or between the employer of a practitioner (a hospital) and a patient. If a health practitioner refers a patient to another practitioner for advice, a new contractual relationship is formed between the second practitioner and the patient. Contractual liability is applicable when a contract has been made concerning protection of a third party such as an unborn child during the delivery process. The issue of contractual liability becomes complicated when more than one health practitioner is involved in an adverse medical event, where a defendant is a health practitioner's assistant, or where a defendant acts under different statuses as an employee, a civil servant or as a private health practitioner. Tortious liability is relevant when a patient is not capable of giving consent to treatment. A health practitioner is liable when he or she fails to fulfill the obligations in tort. Any claims for compensation will follow the general law of compensation of damage laid down in the German Civil Code. For instance, the German Civil Code spells out that a person liable in damages must restore the position that would have existed as if the concerned event had not occurred. In case restoration is not possible, the obligee may request pecuniary damages in lieu of restoration.³⁷²

Sweden³⁷³ runs a no-fault system and injured patients do not have to prove negligence by a health practitioner. The Professional Activities in the Health and Medical Care Field Act³⁷⁴ governs the standard that doctors have to meet when exercising their medical profession in accordance with 'the scientific development and reliable experience'. However, there is no legal definition of this standard, and interpretations have to be derived from administrative provisions governing the professional duties and individual decisions of the Medical Responsibility Board (*Hälso-och sjukvårdens ansvarsnämnd*). A doctor failing to meet this duty, intentionally or negligently, may be subject to the disciplinary actions of the Medical

mín fǎ yuàn guān yú cān zhào 'yī liáo shì gù chǔ lǐ tiáo lì' shěn lǐ yī liáo jiū fēn mín shì àn jiàn de tōng zhī (2003 nián 1 yuè 6 rì)).

³⁷¹ European Commission, Directorate General Information Society (2009) (n 163) 41.

³⁷² Section 249.

³⁷³ European Commission, Directorate General Information Society (2009) (n 163) 43-44.

³⁷⁴ Chapter 2 section 1.

Responsibility Board, including revocation of his or her practising licence. All patients in the private and public sectors are covered by insurance which allows economic compensation for injuries arising from adverse medical events.

In France, there are three basic requirements for medical liability to be established. The first one is negligence or, in the case of no-fault exception, any facts justifying civil liability. The second prerequisite is the victim's injury warranting compensation which is often a loss of a chance. The third requirement is a causal link between the alleged negligence and the victim's injury.³⁷⁵

In Québec of Canada, there are also three prerequisites to meet. First, the defendant has committed a fault. Secondly, the claimant has suffered from harm. Last but not least, there is sufficient causal relationship between the fault and the harm.³⁷⁶

3.4 Telemedicine: A Double-Edged Sword in Health Care

Telemedicine does not escape the risks of alleged clinical negligence. Denning LJ in *Roe v Minister of Health* in the UK said, 'Medical science has conferred great benefits on mankind, but those benefits are attended by considerable risks ... we cannot take the benefits without taking the risks.'³⁷⁷ Advancement of medical science has nourished the growth of telemedicine to provide the needy with healthcare services of enhanced quality,³⁷⁸ but on the other hand it challenges the adequacy of the existing legal framework and safeguards for patients where 'face-to-face consultations remain the gold standard'³⁷⁹ and creates new risks of clinical negligence such as patient safety arising from substandard care provided by unlicensed health practitioners, use of telemedicine to penetrate fraud against patients,

³⁷⁵ Florence G'Sell-Macrez, 'Medical Malpractice and Compensation in France – Part I: The French Rules of Medical Liability Since the Patients' Rights Law of March 4, 2002' (2011) 86(3) Chicago-Kent Law Review 1093, 1097.

³⁷⁶ Lara Khoury, *Uncertain Causation in Medical Liability* (Hart Publishing, Oregon, United States 2006) 26.

³⁷⁷ [1954] 2 QB 66, 83, [1954] 2 All ER 131 (Court of Appeal).

³⁷⁸ Lijuan Lai, Yun Peng, Jing Zhou, and Xiaoming Wu, 'Research of Personalized Medical Testing Technology for Healthy Smart Home' (2010 4th International Conference on Bioinformatics and Biomedical Engineering (iCBBE), Chengdu of China, 18-20 June 2010) 1.

³⁷⁹ Will Marshall, 'Remote Control' *The Lawyer* (United Kingdom, 15 September 2003) <<http://www.thelawyer.com/remote-control/106893.article>> accessed 19 May 2012.

privacy and confidentiality concerns of medical records,³⁸⁰ and the legal uncertainty of liabilities,³⁸¹ etc.

In the context of telemedicine, the use of IT in medical applications has generated further need to review the traditional governmental safeguards, including concerns about how the traditional governmental measures may protect the best interests of patients involved in telemedicine, in particular when there is a lack of legal clarity in areas of licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, and jurisdiction, which poses major challenges to the development of telemedicine in both domestic and cross-border applications.³⁸² In the UK, the General Medical Council, one function of which is to keep up-to-date registers of qualified doctors under the Medical Act 1983,³⁸³ in a project proposal to make sure doctors in the future could regularly demonstrate to the Council that they remain up to date and fit to practise,³⁸⁴ said that the Council has no legal power to request overseas doctors who are not based within the UK and delivering telemedicine services to patients in the UK to register with a regulator in the UK or to take a practising licence. The Council could only request those telemedicine providers to ensure foreign specialists they commissioned are appropriately qualified and regulated and have demonstrated that they are up to date and fit to practise in their home countries.³⁸⁵ In Australia, research revealed that some respondents working in a mental health service would not use email as a means of communication with clients because of their medico-legal concerns.³⁸⁶ Telemedicine also creates additional concerns about quality and patients' safety on top of those conventional healthcare risks, although Stanberry argued that one of the driving forces to develop telemedicine was to enhance risk management and reduction through applications such as decision support software to reduce medical

³⁸⁰ United States, Federal Trade Commission and Department of Justice, *Improving Health Care: A Dose of Competition* (July 2004) Chapter 2, 31-32

<<http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>> accessed 21 February 2012.

³⁸¹ de Bustos, Moulin and Audebert (n 143) 38.

³⁸² Ibid.

³⁸³ General Medical Council of the United Kingdom, 'The Role of the GMC' <<http://www.gmc-uk.org/about/role.asp>> accessed 15 February 2012.

³⁸⁴ Una Lane, 'Revalidation Project Initiation Document' (1st draft 2009) 5 [1.2] <http://www.gmc-uk.org/4a_Annex_C_Revalidation_Draft_Project_Initiation_Document.pdf_25399990.pdf> accessed 15 February 2012.

³⁸⁵ Ibid 10 [2.3].

³⁸⁶ Cartwright and others (n 169) 203.

errors.³⁸⁷ Bashshur has advocated enhancing remote health practitioners' adherence to prevailing professional standards of clinical practice in telemedicine to increase consistency.³⁸⁸

3.5 Chapter Conclusion

Legal principles in relation to clinical negligence are relatively uniformly applied in common law countries including Hong Kong. In different civil law systems, they have their own laws, regulations and practices to deal with adverse medical events. While such difference in the two legal systems has put telemedicine under the spotlight of how to manage medico-legal risks especially when cross-border ehealth services are practised between a common law country and a civil law jurisdiction, telemedicine in turn challenges the laws of both common law and civil law systems in a way that governments have to review their traditional safeguards for people, in particular when telemedicine is considered a less expensive and effective alternative to help improve access to healthcare services and enhance their service quality in both developed and underdeveloped countries.

³⁸⁷ Benedict Stanberry, 'Legal and ethical aspects of telemedicine' (2006) 12(4) *Journal of Telemedicine and Telecare* 166,167.

³⁸⁸ Rashid L Bashshur, 'Telemedicine Effects: Cost, Quality, and Access' (1995) 19(2) *Journal of Medical System* 81, 90.

CHAPTER 4

Medical Liability (1):

Health Practitioner-Patient Relationship and Duty of Care

‘The practitioner who treads the well worn path ...
will usually be safer, as far as concerns legal liability,
than the one who adopts a newly discovered method of treatment.’
— *Crawford v Board of Governors of Charing Cross Hospital*³⁸⁹

4.1 Chapter Summary

This chapter analyzes the first two legal elements of clinical negligence in the context of telemedicine, namely the health practitioner-patient relationship and the duty of care, and tries to anticipate how courts may resolve alleged clinical negligence cases in telemedicine with reference to the existing case law. Issues concerning standard of care, proof of injury and causation in telemedicine will be dealt with in the next chapter.

4.2 Introduction

Telemedicine is an emerging concept but it does not affect common legal principles. It is anticipated that traditional concepts of clinical negligence including the health practitioner-patient relationship and the duty of care will continue to apply in medical adverse events, but such concepts will be considered in the context of ‘less traditional, unique fact patterns which may add a new layer of difficulty to the court’s analysis.’³⁹⁰

4.3 Health Practitioner-Patient Relationship in General

4.3.1 Doctor-Patient Relationship

There is still judicial debate on whether a doctor-patient relationship is fiduciary in nature. The relationship between a doctor and a patient is ‘capable of

³⁸⁹ The Times, 8 December 1953, 293 (Court of Appeal).

³⁹⁰ Jane Chee, ‘Tele-Medical Malpractice: Negligence in the Practice of Telemedicine and Related Issues’ (Centre for Telehealth & e-Health Law, Washing DC 2010) 26.

being characterised as a fiduciary duty’.³⁹¹ McLachlin J in the Supreme Court of Canada said in *Norberg v Wynrib*, to which L’Heureux-Dubé J concurred,

[T]he most fundamental characteristic of the doctor-patient relationship is its *fiduciary* (with emphasis) nature. All the authorities agree that the relationship of physician to patient also falls into that special category of relationships which the law calls fiduciary ... The foundation and ambit of the fiduciary obligation are conceptually distinct from the foundation and ambit of contract and tort ... In negligence and contract the parties are taken to be independent and equal actors ... The essence of a fiduciary relationship, by contrast, is that one party exercises power on behalf of another and pledges himself or herself to act in the best interests of the other.³⁹²

In *Grewal v Sandhu*, Smith J sitting on the Supreme Court of British Columbia said, ‘The relationship between a doctor and a patient is, at least in some respects, a fiduciary one.’³⁹³ On the other hand, the tort of negligence is to be distinguished from a breach of fiduciary duty arising in equity.³⁹⁴ Dunn LJ in the Court of Appeal in *Sidaway v Bethlem Royal Hospital*³⁹⁵ in the UK said that the fiduciary relationship ‘... has never been applied to the nature of the duty which lies upon a doctor in the performance of his professional treatment of his patient ... I do not find it helpful in considering the duty of doctor to his patient to draw analogies ... from other branches of the law ...’³⁹⁶ It may not be easy to further develop the legal concept of fiduciary relationship between a doctor and a patient, in view of the existence of legal difficulties such as what precisely the duties of a fiduciary are and the uncertainty on how such duties should be translated into the doctor-patient relationship.³⁹⁷

³⁹¹ John Powell, Roger Stewart, and Rupert M Jackson (eds), *Jackson & Powell on Professional Liability* (6th edn, Sweet & Maxwell 2007) 908 [13-012].

³⁹² (1992), 68 BCLR (2d) 29, 12 CCLT (2d) 1, [1992] 4 WWR 577, 138 NR 81, 9 BCAC 1, 19 WAC 1, 92 DLR (4th) 449, [1992] 2 SCR 226, [1992] RRA 668, 34 ACWS (3d) 705, JE 92-939, EYB 1992-67036 (Supreme Court of Canada), [64] & [66].

³⁹³ 2010 BCSC 1627, [2011] BCWLD 3215, [2011] BCWLD 3214, [2011] BCWLD 3213, [2011] BCWLD 3246 (Supreme Court of British Columbia), [64].

³⁹⁴ Walton and others (eds) (n 320) 12 [1-20].

³⁹⁵ [1984] QB 493, [1984] 1 All ER 1018 (Court of Appeal).

³⁹⁶ *Ibid* 515.

³⁹⁷ ‘United States [comments]’ (1995) 3 Medical Law Review 209, 218.

One uncontroversial point about a doctor-patient relationship is that subject to exceptional circumstances, the existence of a duty of care owed by a doctor to a patient is the very first condition for a clinical negligence claim against the doctor, which in turn depends on the existence of such a relationship.³⁹⁸ ‘A professional physician-patient relationship is a legal prerequisite of a cause of action for medical malpractice’, said Corrigan J, sitting on the Court of Appeals of Michigan in *Weaver by Weaver v University of Michigan Board of Regents*.³⁹⁹ The same court in *Rogers v Horvath*⁴⁰⁰ also held that no cause of action for malpractice could exist in the absence of a physician-patient relationship.

In hospitals a doctor-patient relationship may arise even before a doctor sees a patient,⁴⁰¹ though there is some lack of uniformity in case law from different jurisdictions. In the US, the pregnant claimant in *Childs v Weis*⁴⁰² attended an emergency room and complained that she was bleeding and had labour pains. A nurse examined her and telephoned the defendant doctor who advised the nurse to ask the claimant to contact her own doctor in another city and had never examined or treated the claimant. The Court of Civil Appeals of Texas ruled that doctors on emergency call had no specific duty to see all patients who presented themselves to the emergency room and the nurse’s conversation with the defendant doctor over the phone did not amount to an acceptance of seeing the claimant.⁴⁰³ However, in the UK, the defendants in *Barnett v Chelsea and Kensington Hospital Management Committee*⁴⁰⁴ received a different court ruling. Three patients suffered from vomiting after drinking arsenic-contaminated tea and attended a casualty department of the defendant hospital. The nurse telephoned a doctor on duty who told her to ask the patients to go home and consult their own doctors. One of the patients died a few hours later from poisoning. Although the doctor had not seen the deceased, Nield J held that the hospital had a ‘close and direct’ relationship with the deceased, and the doctor was under a duty to the deceased to exercise reasonable care.⁴⁰⁵

³⁹⁸ Emily Jackson (n 325) 108.

³⁹⁹ 201 Mich. App. 239, 242, 506 N.W.2d 264 (Mich.App., 1993) (Court of Appeals of Michigan).

⁴⁰⁰ 65 Mich. App. 644, 647, 237 N.W.2d 595 (Mich.App. 1975) (Court of Appeals of Michigan).

⁴⁰¹ Emily Jackson (n 325) 109.

⁴⁰² 440 S.W.2d 104 (Tex.Civ.App., 1969) (Court of Civil Appeals of Texas).

⁴⁰³ Ibid 440 S.W.2d 104, 107.

⁴⁰⁴ [1969] 1 QB 428, [1968] 1 All ER 1068 (High Court Queen’s Bench).

⁴⁰⁵ Ibid [1969] 1 QB 428, 436 (Nield J).

4.3.2 Other Health Practitioners' Relationship with Patients

Health practitioner-patient relationship is not solely confined to doctors and patients. In *Barnett* above, for example, the court also held that the nurse was under a duty to the deceased to exercise reasonable care.⁴⁰⁶ This case has demonstrated that not only doctors will establish a relationship with patients, but other health practitioners such as nurses⁴⁰⁷ do so as well. Pharmacists, for instance, also owe a duty of care to those who seek pharmaceutical products and services.⁴⁰⁸ In *Horner v Spalitto*⁴⁰⁹ in the US, the defendant pharmacist filled a prescription for a strong drug at three times the normal dosage which led to a patient's death and the family claimed medical negligence. The trial court dismissed the action on the ground that the defendant's duty was to fill the prescription accurately. The Missouri Court of Appeals overruled the lower court's decision and held that pharmacists have the skills to notice errors and are in the best position to alert physicians to possible errors, and pharmacists also have a duty to exercise reasonable care.

Third-party health practitioners or institutes may also establish a legal relationship with patients and owe them a duty of care. In *Farraj v King's Healthcare NHS Trust*⁴¹⁰ in the UK, Mr and Mrs Farraj both carried a gene which can cause a disabling blood disorder. Mrs Farraj was advised to undergo DNA testing when she was pregnant for the third time to detect if the child would suffer from the disorder. The first defendant institute received Mrs Farraj's sample and in turn sent it to the second defendant, an independent laboratory, for culturing⁴¹¹ her sample so that the former could carry out DNA testing on it. The independent laboratory returned the cultured sample to the first defendant for testing. The test was negative and the first defendant advised Mr Farraj's obstetrician that the foetus did not carry the blood disorder. Unfortunately the baby was born with the disorder. The Court of Appeal applied the general rule that where a person under a duty of care entrusted the performance of the duty to an apparently competent contractor, he or she was not

⁴⁰⁶ Ibid [1969] 1 QB 428, 436 (Nield J).

⁴⁰⁷ Walton and others (eds) (n 320) 633 [9-183].

⁴⁰⁸ *Lasley v Shrake's Country Club Pharmacy, Inc.*, 179 Ariz. 583, 880 P.2d 1129, 1132 (Ariz.App. Div. 1, 1994) (Court of Appeals of Arizona), as cited in David B Brushwood, 'The Professional Capabilities and Legal Responsibilities of Pharmacists: Should "Can" Imply "Ought"?' (1996) 44(3) Drake Law Review 439, 446.

⁴⁰⁹ 1 S.W.3d 519 (Mo.App. W.D., 1999) (Missouri Court of Appeals, Western District).

⁴¹⁰ [2009] EWCA Civ 1203, [2010] 1 WLR 2139 (Court of Appeal).

⁴¹¹ Culturing is a process to increase the volume of cells and also the amount of DNA to facilitate further analysis.

under a duty to check the contractor's work and was entitled to rely on its proper performance.⁴¹² It was held that the independent laboratory owed a duty of care to the claimants following the incorrect test result and was liable for 100% of the damages and the appellant parents' costs of action. However, there are limits to such a duty as revealed in *Drady v Canada (Minister of Health)*⁴¹³ and *Attis v Canada (Minister of Health)*⁴¹⁴ in Canada. In these two cases, the claimants argued that Health Canada, the federal department responsible for Canadians' health, had a duty of care to protect them from harmful devices, namely TMJ and silicone breast implants. The Ontario Court of Appeal held that Health Canada was not liable to any of the claimants where the Food and Drugs Act imposed the obligation for the safety of a medical device on the manufacturer and distributor. Knowledge alone was insufficient to establish a private law duty of care without any specific representation or reliance on Health Canada.

4.3.3 Health Practitioners' Relationship with Parties Other Than Patients

While it has been recognized that a health practitioner-patient relationship is a prerequisite of a clinical negligence claim, a non-patient third party may make such a claim in some circumstances, as health practitioners may establish a legal relationship with third parties in circumstances such as donor cases, nervous shock, injury through contact with patients, unborn children, and economic loss.⁴¹⁵ *Urbanski v Patel*⁴¹⁶ is a case concerning organ donation in Canada. In this case the defendant doctor mistakenly removed a patient's only kidney, believing it to be a cyst. The patient's father donated one of his kidneys but the transplant was unsuccessful. The kidney had to be removed from the daughter a few days later. The Canadian court distinguished this case from *Sirianni v Anna*,⁴¹⁷ which is a case in the US on very family facts, and upheld the father's claim for damages for the loss of his kidney and the disruption to his life, based on the legal principle of reasonable foreseeability

⁴¹² *D&F Estates Ltd v Church Commissioners for England* [1989] AC 177, [1988] 2 All ER 992 (House of Lords).

⁴¹³ 2008 ONCA 659, 300 DLR (4th) 443, 68 CPC (6th) 306, 270 OAC 1 (Ontario Court of Appeal).

⁴¹⁴ 2008 ONCA 660, 59 CPC (6th) 195, 93 OR (3d) 35, 300 DLR (4th) 415, 254 OAC 91 (Ontario Court of Appeal).

⁴¹⁵ Virginia Dunn (ed), *Professional Negligence Litigation in Practice* (5th edn, Oxford University Press, New York, 2010) 5.

⁴¹⁶ (1978), 84 DLR (3d) 650, 2 LMQ 54 (Manitoba Court of Queen's Bench).

⁴¹⁷ 55 Misc.2d 553, 285 N.Y.S.2d 709 (N.Y. Sup. 1967) (Supreme Court of New York, Niagara County).

of injury to the father. In *Sirianni v Anna*, the plaintiff mother donated voluntarily one of her kidneys to her dying son after the defendant doctors' removal of all his kidneys. The Supreme Court of New York held in 1967 that the mother's 'premeditated, knowledgeable and purposeful [kidney donation] did not extend or reactivate the consummated negligence' of the defendants⁴¹⁸ and she had no cause of action against the defendants for alleged clinical negligence. Ward J sitting on the Supreme Court of New York said, 'The miracle of modern medicine seems now on the threshold of successfully transferring many organs from one human body to another ... If public policy requires that a donor is permitted to maintain a cause of action under the circumstances here, such cause of action must be created, not by judicial fiat, but by legislation ...'.⁴¹⁹ After a decade when medical technologies had advanced, Wilson J said in *Urbanski v Patel* in 1978, 'The word of medicine has progressed beyond the *ratio* (with emphasis) in *Sirianni*, so that ... it was entirely foreseeable that one of [the daughter's] family would be invited, and would agree, to donate a kidney for transplant, an act which accords, too, with the principle developed in the many "rescue" cases.'⁴²⁰ Spencer said *Urbanski* has 'put a new twist on the "egg-shell skull rule"'.⁴²¹

In nervous shock cases, a non-patient third party relative of a patient may become 'a secondary victim' who suffers from psychiatric injury such as post traumatic stress disorder as a result of witnessing a negligent medical treatment of the patient.⁴²² In the UK, the House of Lords held in *Alcock v Chief Constable of South Yorkshire Police* that a defendant will be liable in damages to a claimant for his or her action or omission which has caused or was likely to cause death or injury to a third party if it was reasonably foreseeable that the claimant would suffer a psychiatric illness as a result of the death or injury, whether actual or feared of the third party, and if the claimant has suffered a psychiatric illness which was caused by the death or injury to the third party, whether actual or feared.⁴²³ In order to successfully claim for psychiatric injury arising from a nervous shock, a claimant has to show that (a) the injury was reasonably foreseeable and the relationship between the claimant and

⁴¹⁸ Ibid 55 Misc.2d 553, 556, 285 N.Y.S.2d 709, 712 (N.Y.Sup. 1967) (Ward J).

⁴¹⁹ Ibid 55 Misc.2d 553, 556-557, 285 N.Y.S.2d 709, 713 (N.Y.Sup. 1967) (Ward J).

⁴²⁰ (1978), 84 DLR (3d) 650, 2 LMQ 54 (Manitoba Court of Queen's Bench) [106] (Wilson J).

⁴²¹ J R Spencer, 'Tissue Donors: are They Rescuers, or Merely Volunteers?' (1979) 38(1) Cambridge Law Journal 45, 45.

⁴²² Emily Jackson (n 325) 113.

⁴²³ [1992] 1 AC 310, 349 (House of Lords).

the defendant was sufficiently proximate, (b) the claimant must have a sufficiently proximate relationship with the third party to whom the defendant owed a duty of care, the proof of which was based on ties of love and affection, rather than particular relationship such as husband and wife or parents and children, and (c) the claimant was close in time and space to the accident or its immediate aftermath.⁴²⁴ In *Taylor and Somerset Health Authority*,⁴²⁵ a husband had a heart attack and died because of the negligence of a health authority. The claimant was the wife of the deceased and suffered shock and distress when she was informed of his death and viewed the body. She claimed damages for nervous shock. The trial court applied *Alcock* and dismissed the claim, as the husband's death was arising from the defendants' negligence months ago and there was no external traumatic event which had caused the death. The rule of 'immediate aftermath' allowing claims for nervous shock did not apply. Also, the communication means by which caused the claimant's shock, namely the doctor's verbal communication of the fact of the death and the subsequent viewing of the body where no signs of fatal attack was present, did not fall within the recognized categories allowing the claim for damages.⁴²⁶ *Pang Koi Fa v Lim Djoe Phing*⁴²⁷ shows an example of nervous shock in Singapore. The claimant mother persuaded her daughter to undergo an operation for a misdiagnosed pituitary tumour. The daughter subsequently died and the mother suffered from post traumatic stress disorder and pathological grief. The court distinguished this case from *Alcock* in the UK⁴²⁸ and held that the defendant doctor was found liable to the claimant for 'negligent infliction of psychiatric illness.'⁴²⁹

As for cases involving injury through contact with patients, in the UK, the House of Lords in *Caparo Industries Plc v Dickman*⁴³⁰ held that three factors have to exist for a duty owed to a third party to arise, namely foreseeability of the loss or injury, sufficient proximity to give rise to a duty of care, and the fair, just, and reasonable imposition of a duty of care upon a party for the benefit of the other. Extension of the health practitioner-patient relationship to an unborn child is demonstrated in *Burton v Islington Health Authority*, *de Martell v Merton and Sutton*

⁴²⁴ Ibid 311.

⁴²⁵ [1993] PIQR P262, [1993] 4 Med LR 34 (High Court Queen's Bench).

⁴²⁶ Ibid [1993] PIQR P262, P262.

⁴²⁷ [1993] SGHC 153, [1993] 3 SLR 317 (High Court of Singapore).

⁴²⁸ Ibid [69].

⁴²⁹ Ibid [59].

⁴³⁰ [1990] 2 AC 605, [1990] 1 All ER 568 (House of Lords).

Health Authority,⁴³¹ where the English Court of Appeal ruled that though a foetus did not enjoy an independent legal personality, a health practitioner owes a duty of care to an unborn child if he or she knows or ought to know that a patient is pregnant, and the child has a cause of action at birth for any damages suffered since the birth owing to the pre-natal injuries.

Turning to the issue of economic loss, it is not clear whether a health practitioner owes a duty of care to avoid causing pure financial loss suffered by a third party, and it is difficult to successfully make claims against such loss.⁴³² In *Phelps v Hillingdon LBC*⁴³³ in the UK, one of the claimants successfully established that failure of the employed educational psychologists of the defendant in diagnosing that she had suffered from dyslexia was a breach of the duty of care, which would result in a reduction in her level of achievement and a loss of employment and wages because of her receiving no special schooling. The House of Lords rejected the defendant's argument that any duty owed by its educational psychologists could be owed to them alone.

In addition to the above extension of a health practitioner's duty to third parties, there were also questions as to whether health practitioners should be held negligently liable if their patients cause accidents or commit crimes and whether such liability should be extended to victims and their family members, and if affirmative, how long should a practitioner remain liable after a patient's discharge?⁴³⁴ In the US, the Supreme Court of California in *Tarasoff v Regents of University of California*⁴³⁵ held that the defendant psychotherapists had a duty to use reasonable care in warning the victim when they determined that a patient posed a danger to another. Other states of the US have reacted differently to this case. Over 25 states followed *Tarasoff* either by statutes or by cases since it was held and others deliberately rejected or limited its application.⁴³⁶ This case has also sparked a continuous debate between rules of confidentiality, risk assessments, and a duty to warn a third party

⁴³¹ [1993] QB 204 (Court of Appeal).

⁴³² Powell, Stewart and Jackson (eds) (2007) (n 391) 906-907 [13-011].

⁴³³ [2001] 2 AC 619, [2000] 3 WLR 776 (House of Lords).

⁴³⁴ Fenella Morris and Gwen Adshead, 'The liability of psychiatrists for the violent acts of their patients' (1997) 147 New Law Journal 558, 558.

⁴³⁵ 17 Cal.3d 425, 551 P.2d 334, 131 Cal.Rptr. 14 (Cal. 1976) (Supreme Court of California).

⁴³⁶ Scott Rogge, 'Liability of Psychiatrists under New York Law for Failing to Identify Dangerous Patients' (2000) 20(2) Pace Law Review 221, 224.

since then.⁴³⁷ In *Coombes v Florio*,⁴³⁸ there were two defendants: a patient and a doctor. The defendant patient concerned was 75 years old at the time of a car accident in 2002. Before that, the defendant doctor warned him not to drive for safety reasons during his treatment for cancer. The patient had not driven until 2001 when the treatment was concluded and the doctor advised that he could resume driving. On a day in 2002, the patient fell into unconsciousness while driving and killed a 10-year old child. At the time of the car accident, the doctor had prescribed some drugs with possible side effects of drowsiness, dizziness, light headedness, fainting, altered consciousness, and sedation for the patient. The expert for the claimant testified that the side effects of drugs could be more severe in the elderly and the standard of care required a doctor to warn an elderly or chronically ill patient about the potential side effects of the drugs and the effect on one's ability to drive. The defendant doctor had not warned the defendant patient about this. The child's mother claimed against both the patient and the doctor. The case against the patient was settled following his death in August 2002. The Supreme Judicial Court of Massachusetts reversed the trial court's decision and held that the doctor owed a duty to the claimant under ordinary negligence principles. Cordy J gave a dissenting opinion, as in his view this created a new duty expanding the potential liability of a doctor to someone with whom the doctor has had no contact or relationship and distorted the long recognized legal physician-patient relationship.⁴³⁹ Annas, on the other hand, supported the ruling of *Coombes* and did not think that this case imposed any new obligations on doctors, but rather, the resultant availability of more explicit information about the risks of driving under pharmaceutical influence is beneficial to the society.⁴⁴⁰

4.3.4 Existence of a Relationship?

Although it may be taken for granted that in common law jurisdictions a duty of care exists within the health practitioner-patient relationship,⁴⁴¹ case law has proven to the contrary that the presumption of a duty of care is not always true. Typically, the claimant of an alleged clinical negligence has to prove the existence of

⁴³⁷ Tom Mason, Aidan Worsley and Dave Coyle, 'Forensic multidisciplinary perspectives of Tarasoff liability: a vignette study' (2010) 21(4) *The Journal of Forensic Psychiatry & Psychology* 549, 550.

⁴³⁸ 450 Mass. 182, 877 N.E.2d 567 (Mass., 2007) (Supreme Judicial Court of Massachusetts).

⁴³⁹ 877 N.E.2d 567, 583.

⁴⁴⁰ George J Annas, 'Doctors, Drugs, and Driving -- Tort Liability for Patient-Caused Accidents' (2008) 359(5) *The New England Journal of Medicine* 521, 525.

⁴⁴¹ Emily Jackson (n 325) 108.

a health practitioner-patient relationship and evidence has to establish that the health practitioner in question must have agreed to undertake the care of a patient before such relationship arises. This proof is an issue of material fact. In the US, the Supreme Judicial Court of Massachusetts in *Mary Lou Doherty v Samuel Hellman*⁴⁴² found no record to support the claim that the defendant doctor had agreed to make a diagnosis of the claimant's condition or to have the claimant as his patient, and there were no established facts to allow jurors to determine the existence of a consensual doctor-patient relationship between the parties. In *Hurley v Eddingfield*,⁴⁴³ the Supreme Court of Indiana ruled that the defendant owed no duty to help a seriously ill patient even though he was the patient's family doctor.

4.4 Health Practitioners' Duty of Care in General

A health practitioner has no duty of care towards a patient if he or she has not agreed to undertake the patient's care. Stuart-Smith LJ in *Capital & Counties Plc v Hampshire County Council*⁴⁴⁴ in the UK discussed in obiter a case similar to *Goode v Nash*⁴⁴⁵ in Australia that a doctor who has witnessed a road accident and went to help anyone injured is not under any legal obligation to do so and the relationship of doctor and patient does not arise. However, if the doctor volunteers his assistance, he or she has a duty as a matter of law not to make the victim's condition worse. In *Goode v Nash*, the defendant was a volunteer doctor who negligently caused burns on a patient's eye. If the defendant had not chosen to provide gratuitous assistance, he would not have owed the claimant a duty of care. The crux of a claimant's assertion of the existence of a legal relationship between the parties in an action of clinical negligence is to establish the defendant health practitioner's duty of care. The burden of proof then continues to fall upon the claimant to establish other elements constituting negligence, including the practitioner's breach of the duty and standard of care, proof of claimant's injury and the proximate or real cause of the injury.⁴⁴⁶

Once the existence of a health practitioner-patient relationship is established, the practitioner may owe various types of duty to the patient, e.g. a duty

⁴⁴² 406 Mass. 330, 334-335, 547 N.E.2d 931, 934 (Mass., 1989) (Supreme Judicial Court of Massachusetts, Middlesex).

⁴⁴³ 156 Ind. 416, 59 N.E. 1058 (Ind. 1901) (Supreme Court of Indiana), as cited in Kuszler (n 5) 308, Footnote 109.

⁴⁴⁴ [1997] QB 1004, 1035, [1997] 2 All ER 865 (Court of Appeal) (obiter by Stuart-Smith LJ).

⁴⁴⁵ (1979) 21 SASR 419 (South Australian Supreme Court).

⁴⁴⁶ Leslie Chew, 'Principles of Medical Law' in Quan and others (n 324) 26-32 [2.80] – [2.108].

of candour about procedures and processes in medical care as advocated by the Bristol Royal Infirmary Inquiry in the UK,⁴⁴⁷ and the four-principled moral duties as put forward by Gillon.⁴⁴⁸ In the legal context, a health practitioner may owe contractual duties, tortious duties at common law, statutory duties, and/or civil law duties to a patient. How is the legal scope of duty determined? In the case of tort, it will similarly depend upon the purpose of the rule imposing the duty.⁴⁴⁹ In the case of a statutory duty, the question is answered by deducing the purpose of the duty from the language and context of the statute.⁴⁵⁰

4.4.1 Contractual Duties

In conventional medical practices, a written contract between a health practitioner and a patient is not always in existence and there may not be any express contractual terms.⁴⁵¹ Instead of reliance on a written documentation, a health practitioner and a patient establish a contractual relationship by the implied conduct of both parties that a patient seeing a doctor agrees to pay medical fees in return for medical services and the doctor will provide services to the patient with a reasonable degree of diligence and competence.⁴⁵² It is a breach of contract if any party fails to fulfil the agreed contractual obligations. However, it is not a must that a contractual relationship exists between the parties. In the UK, there is ‘almost certainly’ no contractual relationship between the NHS in England and its non-private patients.⁴⁵³ Even if there is a contractual relationship, an action in contract is not common. Peter Pain J sitting on the Court of Appeal in *Thake v Maurice* said, ‘[The present] case differs from the ordinary ‘medical negligence’ case in that the plaintiffs put their case boldly in contract.’⁴⁵⁴

⁴⁴⁷ United Kingdom, Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* (The Stationery Office, London 2001) 14 [65].

⁴⁴⁸ Raanan Gillon, ‘Medical ethics: four principles plus attention to scope’ (1994) 309(6948) *British Medical Journal* 184.

⁴⁴⁹ *South Australia Asset Management Corp v York Montague Ltd* [1997] AC 191, [1996] 3 All ER 365 (House of Lords) (per Lord Hoffmann).

⁴⁵⁰ *Gorris v Scott* (1873-74) LR 9 Ex 125 (Court of Exchequer).

⁴⁵¹ Chew (n 446) 19.

⁴⁵² *Ibid.*

⁴⁵³ Powell, Stewart and Jackson (eds) (2007) (n 391) 897 [13-003].

⁴⁵⁴ [1986] QB 644, 657, [1986] 1 All ER 479 (Court of Appeal).

4.4.2 Tortious Duties at Common Law

A patient may bring a claim both in contract and tort. In the UK, Lord Bingham of Cornhill sitting in the House of Lords in *Chester v Afshar* said, ‘It is trite law that damage is the gist of the action in the tort of negligence. It is not suggested that it makes any difference whether a claim such as the present [case] is framed in tort or in contract.’⁴⁵⁵ Irrespective of the existence of a contractual relationship, a health practitioner may still owe common law and statutory duties of care to exercise reasonable skill and care,⁴⁵⁶ and his or her common law duty of care in tort is additional to any contractual duties.⁴⁵⁷ In an old English authority, *Gladwell v Steggall*,⁴⁵⁸ Tindal CJ ruled that the defendant doctor who caused disastrous consequence in his treatment to a child patient was liable despite the absence of any contract. The tortious duty exists even when a health practitioner treats a patient gratuitously or entirely on a voluntarily basis.⁴⁵⁹ In *Goode v Nash*,⁴⁶⁰ the South Australian Supreme Court held that a doctor who took part gratuitously at a public glaucoma screening project without pay but caused burns on a patient’s eye was liable for negligence and had to pay damages to the victim. The duty in tort has also been extended to third parties. *A & B v Leeds Teaching Hospital NHS Trust*⁴⁶¹ in the UK ruled that the defendant was under a duty of care to explain the purpose of the post-mortem examination to parents of a deceased child and alert the parents to the possibility of organs being retained.⁴⁶²

4.4.3 Statutory Duties

Health practitioners also assume statutory duties, which are distinguishable from the tort of negligence but which, with the same facts, may be co-extensive with common law duties.⁴⁶³ In the UK, as provided for under s. 13 of the Supply of Goods and Services Act 1982, there is an implied term in a service contract that a health practitioner will carry out healthcare services with reasonable care and skill to

⁴⁵⁵ [2004] UKHL 41, [2005] 1 AC 134, 142 [9] (House of Lords).

⁴⁵⁶ Powell, Stewart and Jackson (eds) (2007) (n 391) 900-901 [13-006].

⁴⁵⁷ Ibid 901 [13-007].

⁴⁵⁸ (1839) 5 Bing NC 734, 132 ER 1283 (Court of Common Pleas).

⁴⁵⁹ Powell, Stewart and Jackson (eds) (2007) (n 391) 901 [13-007].

⁴⁶⁰ (1979) 21 SASR 419 (South Australian Supreme Court).

⁴⁶¹ [2004] EWHC 644 (QB), [2005] QB 506 (High Court Queen’s Bench).

⁴⁶² As cited in Powell, Stewart and Jackson (eds) (2007) (n 391) 901 [13-006].

⁴⁶³ Walton and others (eds) (n 320) 14 [1-25].

patients. In *Samuels v Davis*,⁴⁶⁴ the Court of Appeal held that the appellant dentist was in breach of an implied condition when he failed to make a denture reasonably fit for the purpose for which it was supplied. The nature and extent of this implied statutory duty, as per Lord Hoffmann sitting in the House of Lords in *South Australia Asset Management Corp v York Montague Ltd*, is ‘defined by the term which the law implies, the process is one of construction of the agreement as a whole in its commercial setting.’⁴⁶⁵ In the US, the Missouri Court of Appeals in *Horner v Spalitto* ruled that “in effect, [Section 538.225.1 of the Missouri Revised Statutes] sets the pharmacist’s duty by mandating that his action or omission be judged by his peers according to what ‘a reasonably prudent and careful health care provider would have [done] under similar circumstances.’”⁴⁶⁶

Alongside health practitioners’ duty of care owed to patients, health institutes may also assume statutory duties. In Hong Kong, one of the statutory duties of the Hospital Authority of Hong Kong is ‘to use hospital beds, staff, equipment and other resources efficiently to provide hospital services of the highest possible standard within the resources obtainable.’⁴⁶⁷ Similarly in the UK, section 18 of the Health Act 1999 imposes a statutory duty of quality on all health authorities, NHS trusts and primary care trusts.⁴⁶⁸

4.4.4 Civil Law Duties

Under the civil law system, health practitioners’ duty of care works differently from the common law system. Rather than interpreting law as what is being practised by their counterparts at common law jurisdictions, civil-law judges follow predetermined legal rules⁴⁶⁹ or codified legislation⁴⁷⁰ and applied abstract law

⁴⁶⁴ [1943] KB 526, [1943] 2 All ER 3 (Court of Appeal).

⁴⁶⁵ [1997] AC 191, 212, [1996] 3 All ER 365 (House of Lords) (per Lord Hoffmann)

⁴⁶⁶ 1 S.W.3d 519, 523 (Mo.App. W.D., 1999) (Missouri Court of Appeals, Western District), as cited in Michele Hornish, ‘Just What the Doctor Ordered – Or Was It? : Missouri Pharmacists’ Duty of Care in the 21st Century’ (2000) 65 Missouri Law Review 1075, 1096.

⁴⁶⁷ Hong Kong, Hospital Authority Ordinance (Cap 113), section 4(c)(i).

⁴⁶⁸ Ash Samanta, Jo Samanta and Michael Gunn, ‘Legal considerations of clinical guidelines: will NICE make a difference?’ (2003) 96(3) Journal of the Royal Society of Medicine 133, 135.

⁴⁶⁹ James G Apple and Robert P Deyling, *A Primer on the Civil-Law System* (Federal Judicial Center, United States 1995) 1.

⁴⁷⁰ Stephen J Huang and Anthony S McLean, ‘Do we need a critical care ultrasound certification program? Implications from an Australian medical-legal perspective’ (2010) 14(3) Critical Care 313, 314.

to various cases.⁴⁷¹ In Italy's Civil Code, there has been no specific law for the establishment of a physician-patient relationship and it depends mainly on the Italian Court of Cassation to apply rules to this relationship, which has reaffirmed that public and private doctors have a contractual duty of care to patients, but tort law liability rules are not applicable.⁴⁷² The doctrine of breaching a duty of care does not exist. Rather, the concept of negligent personal injuries (*lesion personali colpose*) not available in common law jurisdictions is employed.⁴⁷³ Other European countries such as Switzerland, Germany, and Belgium have also adopted the contractual approach.⁴⁷⁴ In France, since the judgment of the French Supreme Court in the *Mercier* case⁴⁷⁵ in 1936, which overruled the previous decisions that doctors were liable under tort law,⁴⁷⁶ the physician-patient relationship was also considered a contractual one subject to general civil liability rules.⁴⁷⁷ This legal position has changed since the enactment of the Patients' Rights Law of France on 4 March 2002, which further modified the legal basis for medical liability from a contractual liability to a 'legal regime' that is neither contractual nor tortious,⁴⁷⁸ as confirmed in a recent case of the Supreme Court on 28 January 2010.⁴⁷⁹ In Quebec, though it was influenced by the common law, the sources, methodology, and legal reasoning of the Quebec civil law system work fundamentally differently from other Canadian common law provinces.⁴⁸⁰ Whilst Canadian patients have the option of making a claim in tort or in contract, the latter plays a more important role in Quebec, as it has

⁴⁷¹ de Franchis F *Dizionario Giuridico* (Law dictionary in English), as cited in Francesco Traina, 'Medical Malpractice – The Experience in Italy' (2009) 467(2) *Clinical Orthopaedics and Related Research* 434, 435 and Endnote 8.

⁴⁷² Italian Court of Cassation, United Sections, Judgment n.577, 11 January 2008 and Third Civil Section. Judgment n.589, 22 January 1999, as cited in Traina (n 471) 436, Endnotes 28 and 38.

⁴⁷³ de Franchis F, *Dizionario Giuridico* (Law dictionary in English), as cited in Traina (n 471) 435 and Endnote 9.

⁴⁷⁴ Jacques-Michel Grossen and Olivier Guillod, 'Medical Malpractice Law: American Influence in Europe?' (1983) 6(1) *Boston College International & Comparative Law Review* 1, 5.

⁴⁷⁵ Cour de cassation (Cass.) (Supreme Court for Judicial Matters), judgment of 20 May 1936, DP, 1936, I, 88.

⁴⁷⁶ Mireille Bacache, *La responsabilité médicale sans faute : passé, présent et avenir* (Medical Liability Without Fault: Past, Present, and Future) in (2009) *Liber Amicorum Christian Larroumet* 19, 19; as cited in G'Sell-Macrez (n 375) 1096 and Footnote 22.

⁴⁷⁷ European Commission, Directorate General Information Society (2009) (n 163) 43.

⁴⁷⁸ Bacache (n 476) 20; as cited in G'Sell-Macrez (n 375) 1097 and Footnote 24.

⁴⁷⁹ Cass. 1e civ., Jan. 28, 2010, Bull. civ. I, No. 20; as cited in G'Sell-Macrez (n 375) 1097 and Footnote 25.

⁴⁸⁰ Joan M Gilmour, 'Overview of Medical Malpractice Law in Canada' (1994) 3 *Annals of Health Law* 179, 189.

been established that an *intuiti personae* contract exists between a patient and a doctor.⁴⁸¹

In China, the concept of physician-patient relationship is relatively new to the Chinese legal system and the plan to ‘build a sound and harmonious physician-patient relationship’ was only promulgated in March 2009.⁴⁸² However, it is not clear whether the Chinese version of this relationship is equivalent to the legal relationship between a health practitioner and a patient at common law. As far as the duty of care is concerned, the General Principles of the Civil Law of the People’s Republic of China stipulate that citizens and legal persons will bear civil liability if, through their fault, they encroach on the property of the state, the public or other people or harm other persons.⁴⁸³ Anyone who has caused physical injury to another is liable to pay damages to the victim for medical expenses, loss of income and any disability subsidies if appropriate; in case the victim dies, he or she has is also required to pay funeral expenses, necessary living expenses for the deceased’s dependents and other expenses.⁴⁸⁴ The newly enacted Chinese Tort Law 2010 has further provided that if a medical institution or its medical employee is at fault and makes a patient suffer any harm during diagnosis and treatment, the medical institution assumes compensatory liability.⁴⁸⁵ It also states that a medical institution will not be responsible for compensatory liability for any harm caused to a patient if its medical staff has fulfilled the duty of reasonable diagnosis and treatment in emergency cases⁴⁸⁶ or the diagnosis and treatment of the patient is difficult due to the medical level at the time.⁴⁸⁷ The Chinese HMA Regulation 2002 also governs the handling of claims arising from alleged ‘medical accidents’, details of which are to be elaborated in the next chapter.

⁴⁸¹ Colleen M Flood and Bryan Thomsa, ‘Canadian Medical Malpractice Law in 2011: Missing the Mark on Patient Safety’ (2011) 86(3) *Chicago-Kent Law Review* 1053, 1065.

⁴⁸² China, Central Committee of the Chinese Communist Party and State Council, *Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System* (No. [2009] 6, 17 March 2009) (‘中共中央、國務院關於深化醫藥衛生體制改革的意見 (2009年3月17日，中發[2009]6號)’; *zhōng gòng zhōng yāng · guó wù yuàn guān yú shēn huà yī yào wèi shēng tǐ zhì gǎi gé de yì jiàn* (2009 nián 3 yuè 17 rì, *zhōng fā* [2009] 6 hào)), [13].

⁴⁸³ General Principles of the Civil Law of the People’s Republic of China (中華人民共和國民法通則; *zhōng huá rén mín gòng hé guó mín fǎ tōng zé*), art 106.

⁴⁸⁴ *Ibid* art 119.

⁴⁸⁵ Tort Law of the People’s Republic of China (中華人民共和國侵權責任法; *zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ*) 2010, art 54.

⁴⁸⁶ *Ibid* art 60(2).

⁴⁸⁷ *Ibid* art 60(3).

4.5 Health Practitioner-Patient Relationship and the Duty of Care in Telemedicine

Telemedicine complicates medical claims by challenging the traditional doctrine of clinical negligence in at least three aspects: the health practitioner-patient relationship, the duty of care arising from the relationship, and the standard of care.⁴⁸⁸ The most significant issues for a health practitioner who practises telemedicine are whether he or she owes an online patient a duty of care, which in turn points to the question of health practitioner-patient relationship, and what *standards* (with emphasis) of care would be applicable in telemedical care.⁴⁸⁹ Park and Bashshur pointed out as early as 1975 that telemedicine may change the relationship among health practitioners⁴⁹⁰ and would alter their roles in health care delivery.⁴⁹¹ With the advent of technology, telemedicine has changed not only the relationship among health practitioners, but also refigured their relationship with patients.⁴⁹² In the EU, the European Economic and Social Committee has pointed out that telemedicine affects the doctor-patient relationship and has raised new ethical concerns, and it is crucial to clearly define such a relationship.⁴⁹³

In fact, telemedicine has brought about some practical impact on health practitioner-patient relationship. In the UK, the Privy Council in *Carruthers v General Medical Council*⁴⁹⁴ heard an appeal by a general practitioner against an alleged professional misconduct finding made by the General Medical Council. The appellant doctor gave his advice to a patient by email through a website, based only on the information from the patient's wife on an online checklist, without seeing the patient face-to-face or discussion with the patient's regular general practitioner. The Court allowed the appeal in part and found that the appellant had been guilty of serious professional misconduct but the General Medical Council had imposed disproportionate conditions on his registration. The Court said that the main issue of

⁴⁸⁸ Kuszler (n 5) 307.

⁴⁸⁹ Fleisher and Datta (n 27) 1-47 §1.04[3].

⁴⁹⁰ Ben Park and Rashid L Bashshur, 'Some Implications of Telemedicine' (1975) 25(3) Journal of Communication 161, 161.

⁴⁹¹ Ibid 163.

⁴⁹² Kuszler (n 5) 308.

⁴⁹³ European Union, European Economic and Social Committee, "Opinion of the European Economic and Social Committee on the 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society'" (COM(2008) 689 final; (2009/C 317/15), 2009) [3.3.1.3].

⁴⁹⁴ [2003] UKPC 42, (2004) 75 BMLR 59, [2004] Lloyd's Rep Med 514 (Privy Council).

the case was not the appellant's expertise, nor that had he given improper clinical advice. Rather, 'the real malice was his use of the website and the way in which this led him, without an adequate knowledge of the facts, to interfere with the management of [the patient's] case by his general practitioner.'⁴⁹⁵ Although the Court has not given comments on giving medical advice through a website and *Carruthers* was not a clinical negligence case, it has clearly pointed out that health practitioners have to abide at least by their professional conduct standards in using the virtual environment to see patients.

There is little litigation, if not none, to illustrate how the courts may decide clinical negligence cases in telemedicine. Pendrak and Ericson have pointed out two key legal questions in telemedical practices, including whether a health practitioner-patient relationship exists and whether a practitioner has breached his or her duty.⁴⁹⁶ Kuszler has also made a similar educated guess that courts may follow two lines of case authorities to deal with the issues of the health practitioner-patient relationship involved in adverse telemedicine events, namely whether a health practitioner-patient relationship has been established by the use of telecommunications and which virtual health practitioner in a multiple-specialist consultation has a duty to the patient concerned.⁴⁹⁷ Furthermore, alleged traditional medical events typically occurred within definite time boundaries for an episode of care delivered by an identified physician and any other subsequent specialist consultations also occupied extra time slots identifiable by both patients and doctors, but this is not the case in telemedicine and patients may not be certain as to when a legal relationship has been established with a health practitioner.⁴⁹⁸ Another legal concern lies in the doctrine of informed consent. Traditional clinical negligence actions based on the theory of battery which suggests that a doctor negligently, or even willfully, 'touched' a patient in a harmful or unnecessary manner may not be applied in telemedicine, as there is no physical contact between the parties.⁴⁹⁹ Also, with patients' enhanced access to the Internet, health practitioners who do not pay sufficient attention to patients' medical knowledge which may be culled from the cyberspace may be subject to increased risk

⁴⁹⁵ Ibid [26].

⁴⁹⁶ Pendrak and Ericson, 'Telemedicine and the Law' (1996a) (n 144) 47-48.

⁴⁹⁷ Kuszler (n 5) 308-314.

⁴⁹⁸ Ibid 308.

⁴⁹⁹ Jeff L Magenau, 'Digital Diagnosis: Liability Concerns and State Licencing Issues Are Inhibiting the Progress of Telemedicine' (1997) 19(4) Communications and the Law 25, 33.

of informed consent lawsuits founded upon their ‘failure to discuss therapy at more advanced levels of materiality’ with patients.⁵⁰⁰

In sum, telemedicine may affect the health practitioner-patient relationship in at least five areas: (a) establishment of a legal relationship, (b) breach of the duty of care, (c) the identity of health practitioner(s), (d) uncertainty as to the time of care, and (e) informed consent. Such impact provides ‘an opportunity for the courts to recast the physician/practitioner-patient relationship and the duties that flow from it more flexibly’.⁵⁰¹

4.5.1 Establishment of the Health Practitioner-Patient Relationship in Telemedicine

A practical approach to analyze whether a health practitioner-patient relationship has been developed in a telemedicine setting is to cross reference the practice in the virtual environment with past case precedents in the physical reality, in particular those clinical negligence claims involving telephone consultations, as a patient’s use of a telephone to consult a clinician is the simplest form of telemedicine,⁵⁰² though the Oklahoma Telemedicine Act 1997 of the US expressly excludes a consultation by telephone and facsimile machine from the statutory definition of telemedicine.⁵⁰³ The US case law does provide a wealth of practical references in this regard and Kuszler, for example, has analyzed relevant case law and discussed the issue on whether a legal relationship is established between a health practitioner and a patient over a telephone conversation.⁵⁰⁴ Subsequent to the author’s legal research, it seems that jurisdictions including Australia, Canada, the EU and Hong Kong have had few court cases of direct relevance to this issue.

4.5.1.1 Telephone Consultations among Health Practitioners

The use of telephone for medical consultations can be generally differentiated in two scenarios. They are consultations between health practitioners and consultations between patients and health practitioners. In consultations between

⁵⁰⁰ Frances H Miller, ‘Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship’ (1998) 31(4) *Indiana Law Review* 1019, 1042.

⁵⁰¹ Kuszler (n 5) 308.

⁵⁰² Wootton (1996) (n 9) 1375.

⁵⁰³ §36-6802.

⁵⁰⁴ Kuszler (n 5) 308-310.

health practitioners, the courts have had different decisions as to whether a telephone call will establish a doctor-patient relationship between a consulting doctor and a patient. In the US, case precedents have suggested that consulting physicians do not necessarily form a legal relationship with a patient solely based on consultations between doctors.⁵⁰⁵ The Court of Appeals of Michigan in *Hill v Kokosky*⁵⁰⁶ ruled that an attending doctor's telephone call to another doctor to discuss treatment alternatives will not be sufficient to create a physician-patient relationship between the patient and the doctor consulted. In *Lopez v Aziz*,⁵⁰⁷ the Court of Appeals of Texas found that the defendant physician did not accept any work relating to the patient claimant, did not conduct any laboratory tests or review the results of laboratory tests, did not prepare any reports, and did not bill either the patient or the treating doctor, and decided that a legal relationship had not been established. Similarly, in *St. John v Pope*,⁵⁰⁸ the Supreme Court of Texas overruled the judgment of the appellant court and held that an on-call doctor who advised an emergency room doctor over the telephone and expressed his opinion that a patient should be transferred to another health institute with a specialty that the receiving medical centre in question could not provide did not form a physician-patient relationship. In *Sterling v Johns Hopkins Hospital*,⁵⁰⁹ the Court of Special Appeals of Maryland held that a consulting doctor should not be regarded as a joint provider of medical services for a patient if the treating doctor exercises his or her own independent judgement in deciding to accept the advice of the consulting doctor or not.⁵¹⁰ On the other hand, direct contact is not required as a prerequisite for consulting physicians to establish a doctor-patient relationship with patients.⁵¹¹ In *Lownsbury v Vanburen*,⁵¹² the Supreme Court of Ohio held that a doctor-patient relationship could be formulated between a supervising doctor at a teaching hospital and a patient, despite the fact that the supervising doctor was not actively involved in the care of the patient and had no direct contact with the patient who was actually taken care of by other obstetrics residents.

⁵⁰⁵ Fleisher and Datta (n 27) 1-50 §1.04[3].

⁵⁰⁶ 186 Mich. App. 300, 304, 463 N.W.2d 265 (Mich.App., 1990) (Court of Appeals of Michigan).

⁵⁰⁷ 852 S.W.2d 303, 306 (Tex.App.-San Antonio, 1993) (Court of Appeals of Texas, San Antonio).

⁵⁰⁸ 901 S.W.2d 420, 38 Tex. Sup. Ct. J. 723 (Tex., 1995) (Supreme Court of Texas).

⁵⁰⁹ 145 Md.App. 161, 802 A.2d 440 (Md.App., 2002) (Court of Special Appeals of Maryland).

⁵¹⁰ Ibid 145 Md.App. 161, 187, 802 A.2d 440, 455.

⁵¹¹ Ibid 145 Md.App. 161, 193-194, 802 A.2d 440, 459.

⁵¹² 94 Ohio St.3d 231, 762 N.E.2d 354 (Ohio, 2002) (Supreme Court of Ohio).

4.5.1.2 Patient-Health Practitioner Telephone Consultations

In telephone consultations between patients and health practitioners, a patient's telephone call with a practitioner alone does not necessarily initiate a legal relationship by itself and may not establish a contract between the parties. In the US, the Court of Appeals of Michigan in *Weaver by Weaver v University of Michigan Board of Regents*⁵¹³ examined the effect of a telephone call on the physician-patient relationship and ruled that a telephone call merely to make an appointment with a health practitioner does not establish a doctor-patient relationship. In *Clanton v Von Haam*,⁵¹⁴ the Court of Appeals of Georgia held that the defendant doctor's returning calls to the patient claimant and listening to her symptoms did not establish any physician-patient relationship and that the defendant advised the claimant to see him the next morning did not create a legal relationship, either. Similarly in Minnesota, the jury sitting on the Court of Appeals in *Giles v Sanford Memorial Hospital and Nursing Home*⁵¹⁵ could not reasonably find that a telephone conversation between the defendant doctor and the patient claimant had formed part of a continuing physician-patient relationship, in which no discussion about medication or treatment was made and the patient received no advice. In *Lyons v Grether*,⁵¹⁶ Poff J sitting on the Supreme Court of Virginia held that the claimant's allegation alone that she 'had an appointment with defendant' would not be sufficient to establish a doctor-patient relationship, but her further allegation that the appointment she had been given was 'for treatment of a vaginal infection' was sufficient to form such a relationship and give rise to a duty to perform the service contemplated.⁵¹⁷ In *Bienz v Central Suffolk Hospital*,⁵¹⁸ the Supreme Court of New York held that it is a question of fact for the jury in medical events as to whether a patient's telephone call to a doctor may sufficiently create physical-patient relationship, and whether a patient's reliance on a doctor's advice given over telephone conversation could constitute a legal relationship.

⁵¹³ 201 Mich. App. 239, 242, 506 N.W.2d 264 (Mich.App., 1993) (Court of Appeals of Michigan).

⁵¹⁴ 177 Ga. App. 694, 340 S.E.2d 627 (Ga.App., 1986) (Court of Appeals of Georgia). *Clanton v Von Haam* was distinguished in *Harris v Griffin* 272 Ga. App. 216, 612 S.E.2d 7 (Ga.App., 2005) (Court of Appeals of Georgia) but was not overruled.

⁵¹⁵ 371 N.W.2d 635, 637 (Minn.App., 1985) (Court of Appeals of Minnesota).

⁵¹⁶ 218 Va. 630, 239 S.E.2d 103 (Va. 1977) (Supreme Court of Virginia).

⁵¹⁷ Ibid 218 Va. 630, 633.

⁵¹⁸ 163 A.D.2d 269, 557 N.Y.S.2d 139 (N.Y.A.D., 1990) (Supreme Court of New York).

4.5.1.3 Applications of Telephone Consultation Cases in Other Telemedical Practices

Kuszler generalized three legal principles from the American case precedents which govern the formation of a health practitioner-patient relationship over telephone consultations: whether a health practitioner has agreed to see a patient, whether the contents of telephone conversation are relevant to clinical diagnosis of the patient's health conditions, and whether the patient has relied on the practitioner's advice.⁵¹⁹ These principles may also be applicable in other modern telemedicine applications such as email consultations.⁵²⁰ When all these three principles are fulfilled, a patient who has relied on a health practitioner's online advice obtained from, for example, email communications and later suffered any damage may establish that a health practitioner-patient relationship has been formed for the subsequent cause of actions in a clinical negligence claim.⁵²¹ Similarly, Blum also found three elements underpinning the physician-patient relationship after a review of the case law in the US: contractual, consensual and circumstantial.⁵²² From the perspective of contract, he suggested that in telemedicine, the health practitioner-patient relationship may likely be based on an express contract, as medical websites typically contain details such as express disclaimers and waivers of liability, and in online medicine practised by doctors, further details of the nature of the telemedicine services and requirements for patients' informed consent will be shown to the potential patients in a cyber environment.⁵²³ In the context of consensual relationships, on the patients' side, assuming that health practitioners have made a reasonable disclosure to patients of the risks and benefits, the chance of success and any alternative treatment or procedures, patients' giving informed consent illustrate their willingness to assume risks and to enter into some relation with health practitioners with knowledge that they will receive treatment or procedures bearing clinical risks.⁵²⁴ On the side of health practitioners, in *Irvin v Smith*,⁵²⁵ the Supreme Court of Kansas held that without an on-going doctor-patient relationship, a doctor

⁵¹⁹ Kuszler (n 5) 310.

⁵²⁰ Ibid.

⁵²¹ Ibid.

⁵²² Blum (n 67) 437.

⁵²³ Ibid 438.

⁵²⁴ Robert W Richart, 'Contributory Negligence or Assumption of Risk – What Is a Patient to Do' (1979) 55(2) North Dakota Law Review 237, 248.

⁵²⁵ 272 Kan. 112, 113, 31 P.3d 934, 937 (Kan., 2001) (Supreme Court of Kansas).

has to expressly or impliedly give consent to advise or treat a patient or must take ‘some affirmative action with regard to treatment of a patient’ before a legal relationship is formed. When the legal principle of *Irvin* applies in the context of telemedicine, it means that consensus has to be reached for a health practitioner’s provision of tele-care and a patient’s participation in the online process of treatment before a health practitioner-patient relationship is established.⁵²⁶ In the circumstantial aspect, the question as to whether a legal relationship between a health practitioner and a patient has been established hinges on the specific fact of how the practitioner may have influenced patient care.⁵²⁷ Fleisher and Dechene supplemented this circumstantial perspective that a physician-patient relationship is likely to be established in situations where a doctor sees a patient during a telemedicine visit, where actual examinations have been carried out, where the patient relies on diagnosis, treatment and other care, where the doctor has access to the patient’s medical records, and where the doctor accepts a fee for the telemedical consultation.⁵²⁸

4.5.2 Health Practitioners’ Duty of Care in Telemedicine

In conventional practices, problems in relation to a health practitioner’s duty of care are more likely to arise in cases of advice than in treatment.⁵²⁹ In daily practices health practitioners give not only clinical advice to patients but may also advise other practitioners, and they are subject to different medical liabilities when they advise patients directly and when they consult or advise other health practitioners.⁵³⁰ While telemedicine substitutes traditional face-to-face consultations between doctors and patients, between doctors and doctors, and between doctors and other health practitioners,⁵³¹ the cyber space will not create a protection shield for health practitioners. They are still subject to medical liability arising from their direct advice to patients or when they are involved in consultations between health practitioners.

⁵²⁶ Blum (n 67) 439.

⁵²⁷ Ibid 437.

⁵²⁸ Fleisher and Datta (n 27) 1-48 §1.04[3].

⁵²⁹ Powell, Stewart and Jackson (eds) (2007) (n 391) 902 [13-007].

⁵³⁰ Lynette A Herscha, ‘Is There a Doctor in the House? Licencing and Malpractice Issues Involved in Telemedicine’ (1996) 2 Boston University Journal of Science & Technology Law 89, 105 [36].

⁵³¹ Bashshur (1995) (n 388) 85.

4.5.2.1 Health Practitioners' Giving Direct Advice to Patients

Seeing a patient face-to-face is not a dispositive factor for a health practitioner to create a legal duty of care owed to a patient.⁵³² In the context of telemedicine, the Federation of State Medical Boards in the US gives a guideline that while it may be difficult in an online setting to identify precisely when a health practitioner-patient relationship commences, such a relationship is clearly formulated when a practitioner agrees to undertake diagnosis and treatment and the patient agrees, irrespective of whether there is any personal contact between the parties.⁵³³

4.5.2.2 Consultations among Health Practitioners

Telephone consultation is only one of the clinical communication means between health practitioners. There are in general two main types of consultation formats between health practitioners – formal and informal specialist consultations. Formal consultation is a process by which a treating doctor consults an advising doctor for a written and/or verbal opinion,⁵³⁴ whilst informal consultation takes several forms and ‘curb-side’ consultation is a common medical practice through which a doctor asks for a specialist’s advice without formally inviting the specialist to examine a patient and without the patient engaging the specialist.⁵³⁵ Other informal consultation also occurs in situations where doctors are on call and/or supervise trainee doctors.⁵³⁶ Both formal and informal consultations involve seeking and giving clinical information and various factors affect doctors’ behaviours in the consultation processes, e.g. time constraints, convenience of access, their career stage, locality, and the doctors’ perception on how the information would be able to help solve the clinical issues in question, etc.⁵³⁷ With regard to the issue last mentioned, the House of Lords in *Chapman v Rix*⁵³⁸ in the UK held that the defendant’s omission to send a letter to a deceased patient’s own doctor prior to his death did not constitute

⁵³² *Dougherty v Gifford* 826 S.W.2d 668, 674 (Tex.App.-Texarkana, 1992) (Court of Appeals of Texas).

⁵³³ Federation of State Medical Boards of the United States, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (2002) 4
<http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf> accessed 10 March 2012.

⁵³⁴ Barry C Fox, Michael L Siegel, and Robert A Weinstein, “‘Curb-side’ Consultation and Informal Communication in Medical Practice: A Medicolegal Perspective’ (1996) 23(3) *Clinical Infectious Disease* 616, 616-617.

⁵³⁵ *Ibid* 617.

⁵³⁶ *Ibid*.

⁵³⁷ Cathy M Perley, ‘Physician use of the curbside consultation to address information needs: report on a collective case study’ (2006) 94(2) *Journal of the Medical Library Association* 137, 137-138.

⁵³⁸ [1994] 5 Med LR 239, *Times*, 22 December, 1960 (House of Lords).

negligence, and his verbal instructions to the patient asking him to see and tell his own doctor what the defendant had done to him was sufficient to communicate with the patient's doctor, although it would have been better if the defendant had sent a letter to the patient's doctor.

4.5.2.2.1 Formal Consultations

In formal consultation a healthcare specialist and a patient may establish a legal relationship even if the specialist has not had face-to-face consultation with the patient.⁵³⁹ In Canada, paediatricians of the defendant hospital in *Brown v University of Alberta Hospital*⁵⁴⁰ failed to warn the mother of the claimant (a child) of suspected child abuse based on a radiological scan. In fact, a radioneurologist of the defendant had noticed the claimant's signs of brain haemorrhage owing to violent shaking but did not convey this finding to the paediatricians. The child finally suffered from severe and permanent brain damage after discharge. The court held that there was a doctor-patient relationship between the child claimant and all of the concerned doctors who each owed the claimant a duty of care. The defendant hospital and its employee nurses being sued also owed a duty of care to the claimant.⁵⁴¹ In the US, in *Phillips v Good Samaritan Hospital*,⁵⁴² a treating doctor misdiagnosed that a child patient did not suffer from a fracture. The defendant radiologist later found the fracture, but without explaining the exact reason in court, the correct diagnosis was not conveyed to either the treating doctor or the patient's family doctor. The claimant brought a medical malpractice action against, inter alia, the defendant radiologist who argued that he only provided 'indirect medical care'⁵⁴³ and his liability stopped once he had made a correct medical diagnosis and circulated the same through the hospital system to the treating physician. The Court of Appeals of Ohio held that a physician-patient relationship existed between the patient and the defendant radiologist. He also bore professional responsibilities and duties despite his remote contact with the patient. The court further added that all doctors involved in a case share the same duties and responsibilities as the treating doctor to the extent of their involvement.

⁵³⁹ Kuszler (n 5) 311.

⁵⁴⁰ (1997), 33 CCLT (2d) 113, 48 Alta LR (3d) 1, 197 AR 237, 145 DLR (4th) 63, [1997] 4 WWR 645, 4 WWR 645, [1997] AJ No. 298 (Alberta Court of Queen's Bench).

⁵⁴¹ Ibid [166].

⁵⁴² 65 Ohio App.2d 112, 416 N.E.2d 646 (Ohio App., 1979) (Court of Appeals of Ohio, Second District).

⁵⁴³ Ibid 65 Ohio App.2d 112, 116, 416 N.E.2d 646, 649.

Similarly in *Walters v Rinker*,⁵⁴⁴ the Court of Appeals of Indiana ruled that even though the defendant pathologist did not physically examine, see, treat or prescribe medication for the claimant, a consensual physician-patient relationship existed between the claimant and the defendant pathologist who misdiagnosed a cancerous tumour as benign. In *Dougherty v Gifford*, the appellant pathologist was not employed by the appellant medical association and was only a borrowed staff member. He misinterpreted a patient's biopsy as malignant. The Court of Appeals of Texas held that although the pathologist was employed by others, he met all the requirements of an employee. Also, despite the fact that the pathologist had not met the patient or reviewed the patient's medical records before the adverse event, he had established a consensual doctor-patient relationship with the patient when others had contracted with him for the benefit of the patient.⁵⁴⁵

4.5.2.2.2 Informal Consultations

Informal consultations with other doctors via telephone communications or occurring at 'curb-side' or in corridors for the management of complex cases are not uncommon in medical practices.⁵⁴⁶ In Canada, the trial court in *Bergen v Sturgeon General Hospital*⁵⁴⁷ criticized the informal consultation practices and commented that it is the duty of a hospital authority to devise a proper system to enable health workers to consult specialists. Despite *Bergen*, 'curb-side' consultations may become more prevalent owing to cost-containment considerations.⁵⁴⁸

It is not a straightforward case to conclude if doctors in informal consultations would or would not sufficiently establish a legal relationship with patients.⁵⁴⁹ It depends on how they manage and interact with patients.⁵⁵⁰ In *Reynolds v Decatur Memorial Hospital*,⁵⁵¹ a treating paediatrician called a senior doctor and consulted him about the claimant's case over the phone. The treating doctor performed some tests upon the senior's advice, but misdiagnosed the claimant's conditions. The Appellate Court of Illinois ruled that no doctor-patient relationship

⁵⁴⁴ 520 N.E. 2d 468 (Ind.App. 3 Dist., 1988) (Court of Appeals of Indiana, Third District).

⁵⁴⁵ 826 S.W.2d 668, 675 (Tex.App.-Texarkana, 1992) (Court of Appeals of Texas).

⁵⁴⁶ Fox, Siegel and Weinstein (n 534) 617.

⁵⁴⁷ (1984), 28 CCLT 155 (sub nom *Bergen Estate v Sturgeon General Hospital District No. 100*) 52 AR 161 (Alberta Court of Queen's Bench).

⁵⁴⁸ Fox, Siegel and Weinstein (n 534) 617.

⁵⁴⁹ Kuszler (n 5) 313.

⁵⁵⁰ Ibid.

⁵⁵¹ 277 Ill.App.3d 80, 660 N.E.2d 235, 240 (Ill.App. 4 Dist., 1996) (Appellate Court of Illinois).

existed between the claimant and the defendant senior doctor, who only discussed the claimant's case, gave informal opinion over the phone to the treating paediatrician, had not seen the claimant, and did not bill him for a fee. There was no duty of care owed to the claimant, either. On the other hand, in *Bovara v St. Francis Hospital*,⁵⁵² the deceased patient with a history of heart disease consulted the treating cardiologist and presented a coronary angiogram to the cardiologist which was not taken in the defendant hospital. The cardiologist advised the claimant that he was not skillful in reading the angiogram and referred the angiogram to two cardiac interventionists. The treating cardiologist then received verbal advice from the interventionists' office confirming that the patient was a candidate for coronary angioplasty. Upon receipt of this piece of information the patient agreed to undergo the cardiac procedure but died during the operation. The Appellate Court of Illinois said that '[f]ormality of an opinion is not a determinative test of the presence of a physician-patient relationship'⁵⁵³ and it is a question of fact as to whether the relationship exists and whether the defendant doctor owed a duty of care to the claimant. The Court found that as the treating cardiologist could not interpret the angiogram, he took the advice of the cardiac interventionists seriously and recorded their opinions in the deceased medical record, and that the interventionists' opinion materially affected the cardiologist's advice to the deceased as well as the surgeons who performed the angioplasty operation. The Court ruled that the cardiac interventionists had established a doctor-patient relationship with the deceased and they owed a duty of care to the deceased.

4.5.2.2.3 Impact of Telemedicine on Formal/Informal Consultations

Telemedicine may effectively enhance the opportunity for a health practitioner to establish a legal relationship with a tele-patient. High-tech telemedical equipment may allow a consulting practitioner to be 'virtually present' before a patient, in contrast to the traditional use of a telephone through which a treating practitioner can only speak to a consulting practitioner on a one-to-one basis. In such circumstances, the patient, the treating practitioner and the consulting specialist can see each other and give consent to any examination, diagnosis and treatment.⁵⁵⁴ This

⁵⁵² 298 Ill.App.3d 1025, 700 N.E.2d 143 (Ill.App. 1 Dist., 1998) (Appellate Court of Illinois).

⁵⁵³ Ibid 700 N.E.2d 143, 147.

⁵⁵⁴ Caryl (n 130) 194.

has essentially increased the potential for a consulting practitioner to examine a patient and/or give medical opinions, thus imposing a legal duty of care on the consulting practitioner.

Also, the growth of telemedicine will likely blur the distinction between formal and informal consultations,⁵⁵⁵ as this virtual practice will largely increase the chances of specialist consultations in both formal and informal ways⁵⁵⁶ by breaking territorial frontiers and boundaries between different health practitioners and enabling clinical communication between health practitioners in, for instance, urban and rural areas, which were not practical in the past. The impact of telemedicine on clinical consultations between health practitioners is tremendous. For example, a survey in Iowa of the US found that ‘curb-side’ informal consultations successfully occurred between family doctors and other specialists by the use of emails.⁵⁵⁷ The Oklahoma Telemedicine Act 1997 of the US expressly stipulates that its statutory provisions for patient informed consent do not apply to consultations among or between health practitioners or to other telemedicine interactions in which a patient is not directly involved.⁵⁵⁸ It is also anticipated that the prevalence of a ‘store-and-forward’ mode of telemedicine will prompt more formal consultations and accordingly reduce the proportion of informal consultations.⁵⁵⁹ In fact, ‘the concept of selling medical services worldwide [which was] almost unthinkable to physicians’⁵⁶⁰ has been globally recognized in the ‘nighthawk’⁵⁶¹ and the Indian models of radiological image interpretation services. In the US, nighthawk telemedical providers incorporated in the US enter into contracts with American hospitals to provide telemedical services at the overnight shift to relieve the insufficient number of domestic qualified health practitioners during that shift by deploying other US qualified health practitioners located in different time zones ahead or behind the US in, for example, Sydney or Barcelona.⁵⁶² In contrast to the nighthawk approach, in the Indian model, telemedical

⁵⁵⁵ Kuszler (n 5) 314.

⁵⁵⁶ Ibid.

⁵⁵⁷ G R Bergus, S D Sinift, C S Randall, and D M Rosenthal, ‘Use of an E-mail curbside consultation service by family physicians’ (1998) 47(5) *The Journal of Family Medicine* 357.

⁵⁵⁸ §36-6804.

⁵⁵⁹ Kuszler (n 5) 314.

⁵⁶⁰ Thomas R McLean, ‘The Global Market for Health Care: Economics and Regulation’ (2009) 26(3) *Wisconsin International Law Journal* 591, 591.

⁵⁶¹ ‘Nighthawk’ was named after the first company in the market, the Nighthawk Radiology Services. See Ibid 605, Footnote 90.

⁵⁶² Thomas R McLean, ‘The Future of Telemedicine & Its Faustian Reliance on Regulatory Trade Barriers for Protection’ (2006) 16 *Health Matrix* 443, 449.

providers incorporated in India hire health practitioners in India and provide telemedical services to hospitals in the US also for the overnight shift.⁵⁶³ This Indian model raises jurisdictional concerns, in addition to other considerations on the health practitioner-patient relationship and the practitioners' duty of care in informal and formal consultations. More discussion on the issue of jurisdiction will be made in Chapter 8.

4.5.3 Which Health Practitioners in Telemedicine Are Liable to a Patient?

In the context of telemedicine, a review to the case precedents may provide some tips for the question as to which health practitioner(s) who are involved in a multiple-practitioners telemedicine service would have sufficiently established a health practitioner-patient relationship with a remote patient and therefore owe the patient a duty of care.⁵⁶⁴ In the real-time interaction mode of telemedicine, health practitioners in one location conduct face-to-face consultations with their patients and/or monitor remote patients⁵⁶⁵ in other locations through the Internet in, for example, urban-to-rural situations⁵⁶⁶ or home care services.⁵⁶⁷ In face-to-face consultations, students or other qualified health workers may be present at telemedical consultations for training purposes,⁵⁶⁸ and patients may not be able to identify these trainees. In remote monitoring services, patients may not exactly know which distant health practitioner(s) have actually observed their clinical conditions, as the care may involve more than one practitioner simultaneously. An Electroencephalogram information system provides an example for remote monitoring care, which uses a wireless local area network to facilitate monitoring of a distant patient via the Internet by more than one doctor or alternatively putting more than one patient under surveillance by a remote doctor.⁵⁶⁹

Telemedicine may increase the litigation risk of health practitioners for medical malpractice and expose health institutes to more clinical negligence

⁵⁶³ Ibid 449.

⁵⁶⁴ Kuszler (n 5) 311.

⁵⁶⁵ Santini and others (n 72).

⁵⁶⁶ Dharmar and others (n 74) 562.

⁵⁶⁷ Raad and Yang (n 75).

⁵⁶⁸ Benedict A Stanberry, *The Legal and Ethical Aspects of Telemedicine* (The Seafarers International Research Centre for Safety and Occupational Health at the University of Wales, Cardiff, United Kingdom 1997) 47 [6.12].

⁵⁶⁹ Haifeng Chen and Jungtae Lee, 'The Implementation of a Wireless Electroencephalogram Information System using WLAN' (2008) 8(2) *International Journal of Computer Science and Network Security* 166, 170.

liability.⁵⁷⁰ In the US, the defendant doctor in *Wilson v Teng*⁵⁷¹ only met the claimant (the mother of the deceased) and the deceased child patient socially in an emergency department prior to the patient's discharge and did not participate in the patient care. The trial court dismissed a claim against the doctor based on the view that there was no doctor-patient relationship established in the limited contact between the doctor and the deceased. The Supreme Court of Alabama overturned the summary judgment of the trial court for the doctor. *Wilson* did show that claimants may make a claim against those even with limited contact. In an alleged adverse medical event in telemedicine, if a patient claimant could not identify exactly who has caused the event, this would enhance the technical difficulty of the claim, and the claimant might include those who were not directly involved or even not involved in the tele-care in the claim based on, for example, alleged direct liability, vicarious liability or contributory liability, although this would increase legal costs unnecessarily.

4.5.4 Uncertainty of Time of Care in Telemedicine

When has a tele-doctor established a relationship with his or her patient in a telemedicine consultation?⁵⁷² Patients involved in telemedicine interactions may not necessarily know the definite temporal boundaries of an episode of care, which impacts the establishment of a health practitioner-patient relationship. Contemporary telemedicine applications are mostly made in two patterns, namely 'store-and-forward' mode and real-time interactions.⁵⁷³ In the 'store-and-forward' mode, patients' information such as clinical data, demographic data, and digital images is stored⁵⁷⁴ before the same is forwarded through telecommunication means to another location for peer or specialist consultation.⁵⁷⁵ The time of electronic transmission and the time the transmitted patient information is read by targeting health practitioners may not necessarily be the same,⁵⁷⁶ which is analogous to people's daily behaviour

⁵⁷⁰ Kuszler (n 5) 326.

⁵⁷¹ 786 So. 2d 485 (Ala., 2000) (Supreme Court of Alabama).

⁵⁷² James G Hodge, Lawrence O Gostin and Peter D Jacobson, 'Legal Issues Concerning Electronic Health Information – Privacy, Quality, and Liability' (1999) 282(15) *Journal of the American Medical Association* 1466, 1469.

⁵⁷³ Gillette (n 69) 36.

⁵⁷⁴ See, for example, Logeswaran and Eswaran (n 70) 133.

⁵⁷⁵ Kanthraj and Srinivas (n 71).

⁵⁷⁶ Truls Østbye and Petter Hurlen, 'The Electronic House Call – Consequences of Telemedicine Consultations for Physicians, Patients, and Society' (1997) 6(3) *Archives of Family Medicine* 266, 267.

that emails sent in a morning may only be read at a time convenient to the recipients, irrespective of whether they have immediate access to those emails or not.

Patients' uncertainty of time as to when a health practitioner-patient relationship is established in telemedicine by, say, a doctor's reading a patient's electronic medical record or a nurse's checking a patient's clinical conditions may raise similar disputes that have already occurred in electronic commerce. In those commercial disputes, parties may not agree as to when a contract is established in the virtual environment.⁵⁷⁷ With such a technical difficulty in determining the time of establishing a legal relationship between a health practitioner and a patient involved in telemedicine, it would not be easy for a potential patient claimant to pursue his or her medical claim further.

4.5.5 Informed Consent

Issues on informed consent will be discussed in details in Chapter 6.

4.6 Court's Possible Responses to Telemedicine Claims

For the issue on the establishment of a health practitioner-patient relationship and the duty of care, an examination on the existing case law may give some clues as to the court's possible responses in telemedicine cases involving disputes on whether such a relationship has been established.⁵⁷⁸ Stanberry anticipated that 'in today's legal climate [it] is simply a matter of time' for the first major medical claim against a telemedicine application to arrive,⁵⁷⁹ but Villanueva J sitting on the Superior Court of New Jersey in *Allstate Insurance Co v Northfield Medical Center* pointed out in 2001, 'To date, there has not been a single lawsuit involving the practice of cybermedicine.'⁵⁸⁰ Since Villanueva J made this statement, there have been a lot of developments in telemedicine. In 2009, the Center for Telehealth and e-Health Law of the US reported that a majority of the legal actions in the US brought against tele-health practitioners arose from online prescribing medications across state lines without examining patients in advance, rather than having been as a result

⁵⁷⁷ Rebecca Ong, 'Consumer based electronic commerce: a comparative analysis of the position in Malaysia and Hong Kong' (2004) 12(1) International Journal of Law & Information Technology 101, 104.

⁵⁷⁸ Kuszler (n 5) 310-311.

⁵⁷⁹ Benedict A Stanberry (n 568) 54 [7.2].

⁵⁸⁰ Not Reported in A.2d, 2001 WL 34779104, 35 (N.J. Super. L., 2001) (Superior Court of New Jersey).

of clinical negligence in telemedical practices, and there was no litigation about telemedicine malpractice.⁵⁸¹

As far as the number of lawsuits is concerned, as at the time of writing this thesis, there have still been extremely few alleged clinical negligence cases worldwide in the area of telemedical practices. To check the situation of global litigation, the author conducted online searches at the end of April 2012 by using terminologies of ‘negligence’, and ‘telemedicine’, as well as other possible synonyms of telemedicine including ‘e-health’, ‘ehealth’ ‘telehealth’ ‘tele-health’, ‘mhealth’ ‘m-health’, ‘mobile health’, ‘cybermedicine’, ‘cyber-medicine’, ‘Internet medicine’, and ‘online medicine’ through legal databases of Lexis.com and Westlaw to see if there have been any clinical negligence claims in the context of telemedicine in Australia, Canada, the US, the EU and Hong Kong. After the searches, the author was able to identify only one case in relation to a clinical negligence claim in a setting of telemedicine. In Arizona of the US, in *MacDonald v Schriro*,⁵⁸² the claimant brought an action against the defendant’s alleged medical malpractice in a telemedicine conference, in addition to his alleged deliberate indifference to the claimant’s serious medical needs. The claimant who was an inmate of a prison had injured his left knee twice respectively in 1998 and 2003. Magnetic Resonance Imaging (MRI) was taken in both events. In late 2003, the claimant met the defendant in a telemedicine appointment and he was wearing long pants and remained seated during the whole appointment. The defendant recommended the claimant to continue with his knee brace and anti-inflammatory drugs for pain. The defendant saw the claimant again in 2006 and the claimant underwent knee surgery to remove a loose bone fragment due to a recurrent left meniscus tear. The claimant asserted that the defendant failed to examine his knee and ignored his symptoms in the telemedicine appointment in 2003, failed to read the MRI taken in 2003 despite the claimant’s reminder that the defendant was reading the outdated one taken in 1998, and failed to notice his ‘end-stage’ Hepatitis C that he could not take anti-inflammatory drugs. The District Court of Arizona denied the defendant’s motion for summary judgment and his request for

⁵⁸¹ Christa M Natoli, *Summary of Findings: Malpractice and Telemedicine* (Center for Telehealth & e-Health Law, Washington, United States 2009) 1-3.

⁵⁸² Not Reported in F.Supp.2d, 2008 WL 2783472 (D.Ariz.) (D.Ariz., 2008) (District Court of Arizona).

re-consideration.⁵⁸³ Although *MacDonald* is not especially persuasive or authoritative, the establishment of a legal relationship between the parties in the telemedicine conference was not in dispute, and there are no trial details of this case reported at the time of writing this thesis, it is worth noting that the district judge in *MacDonald* used existing legal principles to assess the defendant's request for summary judgment for both allegations. This case supports the previous scholarly guesses that judges may apply conventional legal principles to claims of alleged medical malpractice in a telemedicine setting and it also tallies with other academicians' views that telemedicine as a new area drawing legal attention, a review to the current legal principles may 'create new patterns of rule-making ... [and] give new coherence to familiar legal phenomena.'⁵⁸⁴ From a practical point of view, courts may continue to apply the current legal principles of medical malpractice cases to test the relationship between parties and the health practitioners' duty of care in telemedicine claims.

4.7 Chapter Conclusion

Telemedicine challenges the traditional doctrine of clinical negligence in at least three aspects: health practitioner-patient relationship, the duty of care arising from the relationship, and the standard of care.⁵⁸⁵ In a telemedical clinical negligence claim, the first two critical issues to consider are whether a tele-health practitioner has established a legal relationship with a tele-patient and whether the former owes the latter a duty of care. If the answers to these two questions are affirmative, it turns the legal attention to another significant issue about which standard of care should be applied in such a claim.⁵⁸⁶

This chapter focuses on the anticipated legal impact of telemedicine on the establishment of health practitioner-patient relationship and the duty of care. Other legal issues embedded in clinical negligence, namely breach of a duty of care, the standard of care, proof of injury, and the proximate or real cause of the injury will be addressed in the next chapter. Owing to the fact that there are few, if not none, clinical negligence claims in the context of telemedicine to deal with the first two

⁵⁸³ *MacDonald v Schriro* Not Reported in F.Supp.2d, 2008 WL 4277828 (D.Ariz.) (D.Ariz., 2008) (District Court of Arizona).

⁵⁸⁴ Michael Pendleton, 'Non-empirical Discovery in Legal Scholarship – Choosing, Researching and Writing a Traditional Scholarly Article' in McConville and Chui (eds) (n 209) 161.

⁵⁸⁵ Kuszler (n 5) 307.

⁵⁸⁶ Fleisher and Datta (n 27) 1-47 §1.04[3].

legal issues worldwide and that a patient's use of a telephone to consult a health practitioner is the simplest form of telemedicine,⁵⁸⁷ traditional case law especially that from the US in relation to consultations using telephone is examined in this chapter.

The issue about whether a health practitioner-patient relationship in a telemedical application is established may depend on the parties' conduct in the tele-encounter, e.g. whether a tele-health practitioner has agreed to see a tele-patient, whether the contents of telemedical communications are relevant to clinical diagnosis of the patient's health conditions, and whether the patient has relied on the practitioner's advice.⁵⁸⁸ Such a legal relationship is likely to be formed where a health practitioner sees a patient during a telemedicine consultation, where actual examinations have been carried out, where the tele-patient relies on the practitioners' diagnosis, treatment and other care, where the practitioner has access to the patient's medical records, and where the practitioner accepts a fee for the telemedical consultation.⁵⁸⁹

Regarding the issue of duty of care, telemedicine likely blurs the distinction between formal and informal consultations by breaking territorial frontiers and boundaries between different health practitioners and increasing the chances of specialist consultations in both formal and informal ways.⁵⁹⁰ This may effectively enhance the opportunity of establishing a legal health practitioner-patient relationship, as a patient, a treating health practitioner and an advising specialist in a telemedical consultation, for example, may see each other through the use of high-tech telemedical equipment and the patient may give consent in the virtual environment to any examination, diagnosis and treatment.⁵⁹¹ This may have in turn increased the likelihood of imposing a legal duty of care on the advising practitioner.

While it seems that telemedicine may boost the establishment of a health practitioner-patient relationship, on the other side of the coin, it increases the technical difficulty of a claimant in establishing his or her case, as in a remote telemedical application, for instance, the claimant may not exactly know which health practitioners are liable and/or is uncertain about the definite temporal boundaries of

⁵⁸⁷ Wootton (1996) (n 9) 1375.

⁵⁸⁸ Kuszler (n 5) 310.

⁵⁸⁹ Fleisher and Datta (n 27) 1-48 §1.04[3].

⁵⁹⁰ Kuszler (n 5) 314.

⁵⁹¹ Caryl (n 130) 194.

an episode of care, which impacts the establishment of a health practitioner-patient relationship.

Clinical negligence litigation in a telemedicine setting is rare worldwide, if not none. Scholars have pointed out that courts may continue to apply the current legal principles of conventional medical malpractice cases to decide the existence of a legal relationship between parties and examine any health practitioners' duty of care in a telemedicine claim. *MacDonald v Schriro*⁵⁹² in Arizona of the US may provide an example of a court's application of existing legal principles in a case with a telemedicine background, though the existence of a health practitioner-patient relationship was not in dispute in the case.

⁵⁹² Not Reported in F.Supp.2d, 2008 WL 2783472 (D.Ariz.) (D.Ariz., 2008) (District Court of Arizona).

CHAPTER 5

Medical Liability (2): Standard of Care, Proof of Injury and Causation

‘The standard of care changes with medical progress.’
—Saul Boyarsky⁵⁹³

5.1 Chapter Summary

At common law, a claimant in a clinical negligence case has to prove that the defendant health practitioner owes a duty of care to him or her, irrespective of whether such duty is tortious and/or contractual in nature,⁵⁹⁴ that the defendant has breached the duty, and that the proximate or real cause of the injury is the defendant’s breach.⁵⁹⁵ The issue of whether a duty is breached is judged by the defendant’s standard of care. In Chapter 4 the duty of care arising from a health practitioner-patient relationship in general and in telemedicine has been discussed. Legal considerations on the standard of care are addressed below in detail. The remaining two elements in a clinical claim, namely proof of the duty of care and causation, will also be briefly discussed.

5.2 Standard of Care in General

Health practitioners have no obligation to guarantee every success in each treating case, except that they undertake the achievement of a specific result.⁵⁹⁶ If they commit a medical mistake, that mistake will not necessarily constitute clinical negligence. While they owe patients a duty of care, they are only obliged to exercise reasonable care and skill, which cannot totally eliminate medical mistakes in situations such as emergency or complex operations. In the US, the Supreme Court of Arizona in *Coburn v City of Tucson*⁵⁹⁷ cautioned the tendency to confuse the concepts of duty and standard of conduct and approved the following postulate of Prosser and Keeton:

⁵⁹³ Saul Boyarsky, ‘Practical Measures to Reduce Medical Expert Witness Bias’ (1989) 34(5) *Journal of Forensic Sciences* 1259, 1263.

⁵⁹⁴ Powell, Stewart and Jackson (eds) (2007) (n 391) 958 [16-066].

⁵⁹⁵ Chew (n 446) 26-32 [2.80] – [2.108].

⁵⁹⁶ *Thake v Maurice* [1986] QB 644, [1986] 1 All ER 479 (Court of Appeal).

⁵⁹⁷ 143 Ariz. 50, 52, 691 P.2d 1078, 1080 (Ariz., 1984) (Supreme Court of Arizona).

It is better to reserve ‘duty’ for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal standard of what is required to meet the obligation. In other words, ‘duty’ is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty [if it exists] is always the same – to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.⁵⁹⁸

In the UK, Lord Edmund-Davies of the House of Lords in *Whitehouse v Jordan*⁵⁹⁹ said, “To say that a surgeon committed an error of clinical judgment is wholly ambiguous, for, while some such errors may be completely consistent with the due exercise of professional skill, other acts or omissions in the course of exercising ‘clinical judgment’ may be so glaringly below proper standards as to make a finding of negligence inevitable.”

5.3 Different Tests of Standards in Different Countries

Medical customs may differ in different countries and in different districts within a country. Different jurisdictions have also had their own measurements of what constitutes a reasonable standard.

5.3.1 Common Law Jurisdictions

In the UK, legal tests of the standard of care have changed over time. Lord President Clyde said in a Scottish case, *Hunter v Hanley*, ‘the true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care.’⁶⁰⁰ Two years after *Hunter*, McNair J in *Bolam v Friern Hospital Management Committee* in England set out the classic *Bolam* test as follows,

⁵⁹⁸ Citing Dan B Dobbs, Robert E Keeton, David G Owen, W Page Keeton, *Prosser and Keeton on the Law of Tort* (5th edn, West Publishing Company, St Paul, Minnesota 1984) 356 §53.

⁵⁹⁹ [1981] 1 WLR 246, 257-258, [1981] 1 All ER 267 (House of Lords).

⁶⁰⁰ [1955] SC 200, 204-205, 1955 SLT 213, [1955-95] PNLR 1 (Court of Session (Inner House)); as cited in Andrew Fulton Phillips, *Medical Negligence Law: Seeking a Balance* (Dartmouth Publishing, England 1997) 17 and Footnote 45.

‘... the test as to whether there has been negligence or not is ... the test of the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art ... he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it another way round, a man is not negligent if he is acting in accordance with such a practice merely because there is a body of opinion who would take a contrary view ...’⁶⁰¹

The House of Lords in *Sidaway v Governors of Bethlem Royal Hospital*⁶⁰² endorsed the *Bolam* test and held that it was applicable to all aspects of health practitioners’ work. According to the principle laid down in *Bolam*, a health practitioner is not guilty of negligence if his or her act or omission is in accordance with a practice accepted as proper by a responsible body of medical experts skilled in that particular form of treatment; nor is the practitioner negligent merely because there is a body of opinion which would adopt a different technique. It does not need a substantial number of ‘responsible medical experts’ for the court to consider if the practice is reasonable under the *Bolam* principle. In *De Freitas v O’Brian*,⁶⁰³ the Court of Appeal held that although the number of specialist doctors supporting the defendant’s position was small (11 versus over 1,000), they were still considered a body of responsible doctors. In *Bolitho v City and Hackney HA*,⁶⁰⁴ the House of Lords ruled that when applying the *Bolam* test, the court has to be satisfied that the experts’ opinion as a reference to the defendant doctor’s standard of care should be ‘responsible, reasonable and respectable’ and was capable of withstanding logical analysis, and the experts had ‘directed their minds to the question of comparative risks and benefits’ and reached a defensible conclusion.⁶⁰⁵ Lord Woolf said, ‘[*Bolitho*] will enable a court to distinguish between two sets of medical opinion.

⁶⁰¹ [1957] 1 WLR 582, 586, [1957] 2 All ER 118 (High Court Queen’s Bench).

⁶⁰² [1985] AC 871, [1985] 1 All ER 643 (House of Lords).

⁶⁰³ [1995] PIQR P281, [1995] 6 Med LR 108 (Court of Appeal).

⁶⁰⁴ [1998] AC 232, [1997] 4 All ER 771 (House of Lords).

⁶⁰⁵ Ibid [1998] AC 232, 241-242 (Lord Browne-Wilkinson).

When faced with conflicting expert evidence, what a court regularly does is to select the reasoning of the expert which is most *logically* (emphasis added) persuasive.⁶⁰⁶ *Bolitho* has made it clear that in considering whether a defendant health practitioner has breached the duty of care, it is for the court to decide if the practice was negligent. The court is not obliged to hold the defendant not liable for negligence simply because medical experts believe that the defendant's act or omission has conformed to accepted medical practice. The defendant's standard of care has to be judged by reference to the *Bolam* test as modified by *Bolitho*.

In the US, the 10th Amendment to the Constitution empowers each state to enact measures to protect the safety, health, welfare and morals of citizens within state borders. As a result of this state autonomy, different standards exist in various states⁶⁰⁷ and have a bearing on clinical negligence lawsuits. Courts have made use of a concept of 'locality' under which a doctor's standard of care is judged by the practices within the profession in general or among a geographically circumscribed subset of his or her colleagues.⁶⁰⁸ This locality rule, 'in its early form, was demonstrably calculated to protect the rural and small town practitioner, who was presumed to be less adequately informed and equipped than his big city brother.'⁶⁰⁹ There are different standards to judge an American doctor's negligence: the community standard and the national standard.⁶¹⁰ Doctors subject to the community standard exercise the same degree of care ordinarily exercised by other doctors in the same or a similar community, whilst those subject to the national standard have to exercise a similar base of knowledge and skill throughout the whole US nation and within the same specialty.⁶¹¹ The community standard of care in the US varies from state to state. In Oregon, for instance, its Medical Practice Act stipulates that a doctor licensed to practise medicine or podiatry by the Oregon Medical Board has 'the duty to use that degree of care, skill and diligence that is used by ordinarily careful [doctors] in the same or similar circumstances in the community of the physician or

⁶⁰⁶ The Right Honourable the Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) 9(1) Medical Law Review 1, 11.

⁶⁰⁷ Catherine Becker, 'A license without borders' (2006) 83(4) Association of Operating Room Nurses Journal 958, 958.

⁶⁰⁸ Kuszler (n 5) 315.

⁶⁰⁹ Jon R Waltz, 'The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation' (1968-1969) 18(2 & 3) DePaul Law Review 408, 410.

⁶¹⁰ Jay M Zitter, 'Standard of care owed to patient by medical specialist as determined by local, "like community," state, national, or other standards' (1982) 18(4th) American Law Reports 603, 608-619.

⁶¹¹ Ibid 606-619.

podiatric physician and surgeon or a similar community'.⁶¹² In North Carolina, according to its General Statutes, a defendant health provider is not liable unless it is evident that his or her care 'was not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities under the same or similar circumstances at the time of the alleged act giving rise to the cause of action ...'.⁶¹³ Alabama,⁶¹⁴ Arizona⁶¹⁵ and Idaho⁶¹⁶ are other examples practising the community standard. Case law in recent decades has helped boost the national standard in the US. In *Morrison v MacNamara*,⁶¹⁷ the District of Columbia Court of Appeals held that the trial judge erred in instructing the jury to compare the defendants' conduct solely with the standard of care prevailing in the District of Columbia and that the national standard should be at least applied to those board-certified physicians, hospitals, medical laboratories and other health care providers. In *Hall v Hilbun*,⁶¹⁸ the Supreme Court of Mississippi evaluated the utility of the locality rule and relied heavily on technological advancements as the foundation for its repudiation of the locality rule.⁶¹⁹ This ruling began a nationwide judicial departure from the locality rule and replaced the locality rule with a national standard of care, recognizing the importance of technology in medical knowledge and training.⁶²⁰ Oklahoma,⁶²¹ Connecticut⁶²² and Florida,⁶²³ for example, follow the national standard.

In Canada, the law relating to clinical negligence is established 'almost exclusively' at the provincial level, which has led to differences across the country in matters of legislation and procedures, for instance.⁶²⁴ In terms of the standard of care, a claimant alleging clinical negligence has to establish that the defendant health

⁶¹² §677.095 sub-section (1).

⁶¹³ United States, North Carolina General Statutes §90-21.12.

⁶¹⁴ United States, the Code of Alabama 1975 §6-5-548.

⁶¹⁵ United States, Arizona Revised Statutes §12-563.

⁶¹⁶ United States, Idaho Statutes §6-1012.

⁶¹⁷ 407 A.2d 555 (D.C., 1979) (District of Columbia Court of Appeals).

⁶¹⁸ 466 So.2d 856 (Miss., 1985) (Supreme Court of Mississippi).

⁶¹⁹ Amy Jurevic Sokol and Christopher J Molzen, 'The Changing Standard of Care in Medicine: E-health, Medical Errors, and Technology Add New Obstacles' (2002) 23(4) *The Journal of Legal Medicine* 449, 475-476.

⁶²⁰ *Ibid* 475-476.

⁶²¹ United States, Oklahoma Code 2010 §76-20.1.

⁶²² United States, General Statutes of Connecticut (2011) §52-184c.

⁶²³ United States, Florida Statutes (2011) §766.102.

⁶²⁴ Gerald B Robertson, 'The Efficacy of the Medical Malpractice System: A Canadian Perspective' (1994) 3 *Annals of Health Law* 167, 168.

practitioner's conduct fell below the applicable standard of care.⁶²⁵ In *Crits v Sylvester*, the Court of Appeal of Ontario held that the standard of care was '[the] degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing.'⁶²⁶ In *Mikhail v Northern Health Authority*, Brown J in the Supreme Court of British Columbia said, '[in clinical negligence cases, health professionals] are judged based on what the court finds is the professional standard of care expected of them, not an amorphous ideal.'⁶²⁷

5.3.2 Civil Law Jurisdictions

In China, the Chinese legal system has outlined a different approach from the common law system as to how to decide whether a clinical act or omission would constitute a breach of the standard of care and cause the statutorily defined 'medical accident'. The Chinese Tort Law 2010 provides that a medical institution shall assume compensatory liability when its medical staff member fails to fulfill the obligations of diagnosis and treatment up to the standard at the time of the diagnosis and treatment and causes any harm to a patient.⁶²⁸ In accordance with the Chinese HMA Regulation 2002, either an administrative department of health or both parties to a medical dispute (on a joint basis) will appoint a society of medical sciences to provide *technical authentication* (professional assessment) of a medical claim⁶²⁹ initially at a local level, the result of which will be re-assessed by a society of medical sciences at the level of provinces, autonomous regions or municipalities directly under the Central Government.⁶³⁰ For difficult or complicated medical disputes of national significance, the Chinese Medical Association⁶³¹ will organize technical authentications.⁶³² These societies of medical sciences must set up databases consisting of experts who have good professional knowledge and excellent professional ethics and are employed by a medical institution or institution of medical

⁶²⁵ Gilmour (1994) (n 480) 190.

⁶²⁶ (1956), [1956] OR 132 (Ontario Court of Appeal), [13] (Schroeder JA).

⁶²⁷ 2010 BCSC 1817, [2011] BCWLD 2527, [2011] BCWLD 2526, [2011] BCWLD 2474, [2011] BCWLD 2473, [2011] BCWLD 2471, 7 CPC (7th) 132 (Supreme Court of British Columbia), [108].

⁶²⁸ Tort Law of the People's Republic of China (中華人民共和國侵權責任法; *zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ*) 2010, art 57.

⁶²⁹ China, Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 20.

⁶³⁰ Ibid art 21.

⁶³¹ '中華醫學會' (*zhōng huá yī xué huì*) in Chinese.

⁶³² China, Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 21.

teaching or research and holding a senior professional title for three years or more. Any legal medical expert who has good professional knowledge and excellent professional ethics and holds a senior professional title may also be included in the database of experts.⁶³³ In general, parties to a medical dispute will select, on a random basis, experts from the database of a society of medical sciences responsible for the technical authentication. Under special circumstances the parties may select experts, again on a random basis, from the databases of other societies of medical sciences.⁶³⁴ The experts so selected must follow the laws, regulations, ministerial rules concerning health and the standards or conventions of medical treatment and nursing, make use of medical principles and professional knowledge to assess the medical accidents independently, make authentications and judgments of the accidents, and provide a medical basis for the settlement of medical disputes.⁶³⁵ A member of the expert panel must attest to the fact that he or she does not have any conflict of interest with the parties, and has to withdraw from the authentication process if he or she is a party or a close relative of a party to the medical dispute, or has interests in the dispute, or has other relationship with the parties that may affect the impartiality of the authentication.⁶³⁶ There is recent debate on whether medical superintendents in China could join the expert database. In Beijing, in order to avoid any potential conflict of interest, the Beijing Medical Association has proposed that no medical superintendent of hospitals there should be appointed experts for any technical authentication of medical incidents. Others have had a different view that almost all medical superintendents are senior clinicians and experienced healthcare management staff. Without the input of these experienced experts, the root cause of a medical incident may not be assessed from a macro point of view.⁶³⁷

In France, a doctor is required to give his patient ‘cautious, attentive and conscientious care in conformity with acquired medical knowledge.’⁶³⁸ The French courts have made use of the concept of the ‘wary physician’ (*médecin avisé*) to decide

⁶³³ Ibid art 23.

⁶³⁴ Ibid art 24.

⁶³⁵ Ibid art 27.

⁶³⁶ Ibid art 26.

⁶³⁷ ‘Medical superintendents are prohibited to join expert authentication groups in medical incidents to avoid “conflict of interest”’ (‘醫療事故鑒定組禁止聘醫院院長 避免“包庇”嫌疑’; ‘yī liáo shì gù jiàn dìng zǔ jìn zhǐ pìn yī yuàn yuàn zhǎng bì miǎn “bāo bǐ” xián yí’) *Jinghua* (China, 17 July 2009) <<http://health.sohu.com/20090717/n265280994.shtml>> accessed 23 January 2012.

⁶³⁸ *Mercier* case Cour de cassation (Cass.) (Supreme Court for Judicial Matters), judgment of 20 May 1936, DP, 1936, I, 88; as cited in Grossen and Guillod (n 474) 7 and Footnote 50.

whether a defendant health practitioner has behaved as a prudent practitioner in the same field would have under the same circumstances. If not, the defendant is negligent.⁶³⁹

5.4 Standard of Care in Telemedicine

Medical technological development affects health practitioners' standard of care as discussed in *Hall v Hilbun*⁶⁴⁰ above. Telemedicine being medical practices without frontiers may have put health practitioners in a position facing different standards of care and thus different tests as to whether an act or omission would constitute clinical negligence. In other words, telemedicine enables health practitioners to practise in a new platform but it also brings questions concerning what standard of care is 'accepted' and what other standards are 'applicable' in telemedical applications,⁶⁴¹ and how courts might decide a claim of alleged clinical negligence in telemedicine.⁶⁴² Although Kauger J sitting on the Supreme Court of Oklahoma in *Johnson v Hillcrest Health Centre* said, '... we refrain from commenting on whether the standard of care would be different today, given the increased implementation of computer technology in the medical profession since that time',⁶⁴³ the Court of Appeals of Maryland in *Shilkret v Annapolis Emergency Hospital Association*⁶⁴⁴ has gone beyond a traditional approach and said that the standard of care should reflect the accessibility of modern communications and improved access to medical and scientific information. Despite different court responses, it is generally recognized that following these years of development, a number of factors have to be taken into account when considering whether a health practitioner has breached the standard of care in a telemedicine practice. In addition to the conventional factors, namely medical knowledge at the material time of an alleged clinical negligence, the practitioner's status, and the practitioner's specialty of practice,⁶⁴⁵ two more factors relevant to telemedicine may have direct bearing on the standard of care in a clinical negligence claim: new concerns about the standard of

⁶³⁹ As cited in Grossen and Guillod (n 474) 7.

⁶⁴⁰ 466 So.2d 856 (Miss., 1985) (Supreme Court of Mississippi).

⁶⁴¹ Fleisher and Datta (n 27) 1-34 §1.04.

⁶⁴² Herscha (n 530) 104 [33].

⁶⁴³ 70 P.3d 811, 2003 OK 16 (Okla., 2003) (the Supreme Court of Oklahoma), Footnote 20 (Kauger J).

⁶⁴⁴ 276 Md. 187, 199, 349 A.2d 245, 252 (Md. 1975) (Court of Appeals of Maryland).

⁶⁴⁵ Dunn (ed) (2010) (n 415) 10.

care arising from telemedicine, and the standards in the home and the remote territories involved in a telemedicine practice.

5.4.1 Medical Knowledge at the Material Time of an Alleged Clinical Negligence

The court takes into account the professional knowledge at the relevant time of complaint when a defendant health practitioner acted or omitted to act. Any medical advancement between the date of the alleged negligence and the date of trial should not be taken into account. In *Roe v Minister of Health*,⁶⁴⁶ the Court of Appeal in the UK found that the plaintiffs' permanent paralyses after surgical operations were caused by a contaminated compound used for anaesthesia and at the date of the operations the risk of such contamination was not appreciated by competent anaesthetists in general. It was held that the standard of knowledge was to be imputed to competent anaesthetists at the time of operations and the defendants were therefore not guilty of negligence in failing to realize the contamination risk. To decide the state of knowledge a court will make reference to expert evidence and literature available at the relevant time, though Mitchell J in *Gascoigne v Ian Sheridan & Co*,⁶⁴⁷ a case alleging negligence against solicitors and a barrister found upon the claimant's failure of her medical negligence claim against a hospital authority, said obiter that a doctor is not obliged to read every publication.⁶⁴⁸

Telemedicine has an impact on a court's making reference to the medical literature and knowledge at the time of an alleged medical malpractice. The Internet provides great convenience for people to get access to such literature and knowledge, but it may simultaneously increase their vulnerability to misleading information. The Medical Council of Hong Kong, for instance, has warned that people seeking medical advice may be vulnerable to persuasive influence and misleading advertisement,⁶⁴⁹ and it has restricted the ways doctors may disseminate information such as 'the more subjective features of advertising'⁶⁵⁰ or 'laudatory material'.⁶⁵¹ Also, the Internet has

⁶⁴⁶ [1954] 2 QB 66, [1954] 2 All ER 131 (Court of Appeal).

⁶⁴⁷ (1994) 5 Med LR 437.

⁶⁴⁸ Dunn (ed) (2010) (n 415) 11.

⁶⁴⁹ Medical Council of Hong Kong, *Code of Professional Conduct for the Guidance of Registered Medical Practitioners* (Revised in January 2009) [5.1.3].

⁶⁵⁰ *Kwok Hay Kwong v Medical Council of Hong Kong* [2008] 3 HKLRD 524, [2008] HKEC 137, [39] (Court of Appeal) (Ma CJHC).

⁶⁵¹ *R v General Medical Council, ex parte Colman* [1990] 1 All ER 489, 493f, (1990) 2 Admin LR 469 (Court of Appeal) (Ralph Gibson LJ).

created a 'standard of care minefield'⁶⁵² for health practitioners in at least two areas. It has influenced patients' perception of their health practitioners' standard of care and it may affect the standard of care of 'an ordinary competent man exercising that particular art' as cited in *Bolam*⁶⁵³ or 'a normal, prudent practitioner of the same experience and standing' as in *Crits*⁶⁵⁴ above.

First, the Internet may change how patients or claimants perceive health practitioners' standard of care, and this may put the practitioners in a more vulnerable position subject to lawsuits. The Internet is changing the balance of power between patients and health practitioners, as patients are empowered through improved access to specialist knowledge.⁶⁵⁵ With the explosion of Internet access and the ubiquitous computing environments worldwide, it is easier for patients to get medical information at their fingertips than any time in the past. There are in fact a large number of people surfing the Internet to look for health information. For instance, Grandinetti reported that there were over 70,000 websites containing health information⁶⁵⁶ and the Pew Internet and American Life Project found that about 60 million Americans checked health-related information.⁶⁵⁷ A patient may see a doctor with medical information they have found online and the doctor has to justify if he or she disagrees with the patient's self-diagnosis or deviates from any treatment the patient expects to receive.⁶⁵⁸ Patients and/or claimants may rely on online health information to argue for their alleged claims. In Canada, the claimant in *Thompson v Zeldin* conducted his own research about his disease by discussing his symptoms with similar patients and reviewing medical websites and concluded that his symptoms were 'major, common and well-known' risks associated with the surgery he underwent and should have been disclosed to him by his doctor prior to the

⁶⁵² Sokol and Molzen (n 619) 478.

⁶⁵³ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

⁶⁵⁴ (1956), [1956] OR 132 (Ontario Court of Appeal).

⁶⁵⁵ J A Powell, M Darvell and J A M Gray, 'The doctor, the patient and the world-wide web: how the Internet is changing healthcare' (2003) 96(2) *Journal of the Royal Society of Medicine* 74, 75.

⁶⁵⁶ Cited in Shelia R Cotton and Sipi S Gupta, 'Characteristics of online and offline health information seekers and factors that discriminate between them' (2004) 59(9) *Social Science & Medicine* 1795, 1797.

⁶⁵⁷ Lee Rainie and Dan Packel, 'More online, doing more' (The Pew Internet & American Life Project, Washington DC 2001) 7

<http://www.pewinternet.org/~media/Files/Reports/2001/PIP_Changing_Population.pdf.pdf>
accessed 20 February 2012.

⁶⁵⁸ Deirdre Madden, 'Empowering health information: medico-legal issues' (2002) 8(1) *Medico-Legal Journal of Ireland* 7, 7.

surgery.⁶⁵⁹ Murray and her colleagues' survey may further shed light on this issue.⁶⁶⁰ They conducted a survey involving 3,209 respondents and found that 97% of the respondents believed that health information on the Internet gave patients more confidence to talk to a doctor about their concerns, 93% said that such information challenged doctors to be more up-to-date with the latest treatments, and 22% thought that it could interfere with the physician-patient relationship. People who used the Internet frequently for finding health information were more likely to expect their doctors to do something specific than those who seldom used it (32% vs. 14%), and 50% of the frequent-user group rated their regular doctors' care as 'fair or poor' rather than 'good, very good, or excellent', whilst only 27.5% of the seldom-user group did so. In that survey, out of 513 respondents who had found information relevant to their own health, 256 (50%) had taken the information to their doctors and among those 256 people, 15% said that their doctors had 'acted challenged' when they brought in the health information from the cyberspace, 12% sought a second opinion from another doctor, 4% changed their physicians, and 1% changed their health plan.⁶⁶¹ Although Murray's survey was not targeted at finding whether the availability of online health information would increase the litigation risk of health practitioners because of an alleged breach of the standard of care, it did provide an interesting picture of how patients may perceive their doctors' standard of care with the 'help' of health materials they culled from the Internet. In fact, there have been debates on whether the public's use of the Internet to look for medical information will 'de-professionalise' medicine,⁶⁶² and health practitioners will start to feel threatened by this behaviour.⁶⁶³

Secondly, online health information may change the standard of care, especially when the court sees it as reliable as the conventional literature. Health practitioners have a duty to stay current with medical developments, which has become much more difficult than before, as the speed of development of medical

⁶⁵⁹ (2008), [2008] OJ No. 3591, 169 ACWS (3d) 657 (Ontario Master), [20]-[23].

⁶⁶⁰ Elizabeth Murray, Bernard Lo, Lance Pollack, Karen Donelan, Joe Catania, Martha White, Kinga Zapert and Rachel Turner, 'The Impact of Health Information on the Internet on the Physician-Patient Relationship' (2003) 163(14) *Archives of Internal Medicine* 1727.

⁶⁶¹ *Ibid* 1731-1732.

⁶⁶² Michael Hardey, 'Doctor in the house: the Internet as a source of lay health knowledge and the challenge to expertise' (1999) 21(6) *Sociology of health & illness* 820.

⁶⁶³ Mary Malone, Ruth Harris, Richard Hooker, Tina Tucker, Nuttan Tanna and Sasha Honnord, 'Health and the Internet-changing boundaries in primary care' (2004) 21(2) *Family Practice* 189.

knowledge has accelerated.⁶⁶⁴ In *Harbeson v Parke-Davis, Inc.*,⁶⁶⁵ the Supreme Court of Washington upheld the decision of the trial judge that the defendant physicians breached their duty of care by failing to conduct a literature search regarding the correlation between an anticonvulsant drug and birth defects, and that this breach was a proximate cause of the claimant's injury – the birth of two children who suffered from 'fetal hydantoin syndrome' with symptoms such as growth and developmental deficiencies, wide-set eyes, drooping eyelids, and other physical defects, etc. Nowadays in an alleged medical adverse event, a potential claimant may guess, if not check, the possible causes in the aftermath through searches on the Internet. He or she may tend to think that the health practitioner in question should have read what has been available on the Internet and considered those online materials in the patient care process; or else, the practitioner must have been negligent in the event. In such a case, the health practitioner may argue that he or she should not bear any liability as it 'inappropriately and unjustly equate[s] awareness of medical information with knowledge of that information'.⁶⁶⁶ The health practitioner may further argue that even if he or she has read the online medical references as held by the claimant as 'material' in a concerned case, mere reading of medical literature alone would not have necessarily provided the practitioner with actual working knowledge of the medical techniques described therein,⁶⁶⁷ which could only be acquired through actual clinical practice and evaluation.⁶⁶⁸

If a potential claimant were to think a health practitioner should be liable because he or she has not read medical references available in the Internet, it would be more likely than not that they would seek legal advice and/or bring an action for clinical negligence and would wish to submit the online health materials to the court as evidence or even as 'expert' evidence. This raises two issues, namely admissibility and reliability of online health materials and how much weight a court would assign to these materials. Case law in the US may give a clue to these two issues. In a

⁶⁶⁴ Sokol and Molzen (n 619) 478.

⁶⁶⁵ 98 Wash.2d 460, 656 P.2d 483 (Wash., 1983) (Supreme Court of Washington).

⁶⁶⁶ Donald E Kacmar, 'The Impact of Computerized Medical Literature Databases on Medical Malpractice Litigation: Time for Another *Helling v. Carey* Wake-Up Call?' (1997-1998) 58(2) Ohio State Law Journal 617, 653.

⁶⁶⁷ Thomas J Harlan, 'Statewide Standard of Care in Medical Malpractice Cases – We're Shoveling Smoke' (1983-1984) 18(2) University of Richmond Law Review 361, 372.

⁶⁶⁸ Ann Lennarson Greer, (1988) 4(1) 'State of the Art Versus the State of Science: The Diffusion of New Medical Technologies into Practice.' International Journal of Technical Assessment in Health Care 5, 23, as cited in Kacmar (n 666) Footnote 213.

clinical negligence case, a court may in general consider how a new technology has impacted on medical custom⁶⁶⁹ and at what point legal liability attaches to those new medical information or practices. The court's analysis may involve, for example, whether a new practice has been accepted in the daily practice, when the information is available on the Internet and incorporated into hospital practice, where the specialists of the same profession make use of that information as a practice guideline, and when an expert swears under oath that it has been the accepted custom of the profession, etc.⁶⁷⁰ The easy availability of the Internet has been 'a powerful temptation' for the court.⁶⁷¹ Lee said that there has been a tendency for American courts to cite more and more online sources in their reported opinions, the examples of which included the first citation by a federal judge in 1996, 32 citations in federal and state court decisions between January 2004 and August 2006, the Supreme Court's citing of a legal blog in 2005, and 13 more by the end of July 2007.⁶⁷² Peoples pointed out that the US courts have also cited Wikipedia⁶⁷³ in over 400 judicial opinions.⁶⁷⁴ Actually, the courts in the US treat online materials differently. In *Campbell v Secretary of Health & Human Services*,⁶⁷⁵ the Court of Federal Claims found that the Internet articles (essentially from Wikipedia) the special master culled from the Internet did not remotely fulfil the reliability requirement for scientific evidence as held in *Daubert v Merrell Dow Pharms.*⁶⁷⁶ It vacated the special master's decision and remanded the case to the Office of Special Masters for further proceedings. In *Daubert*,⁶⁷⁷ the Supreme Court of the US has held that the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. In another case, *Alfa Corp. v OAO Alfa Bank*, the District Court of New York did not follow *Campbell*⁶⁷⁸ and the magistrate judge said,

⁶⁶⁹ *Harbeson v Parke-Davis, Inc.* 8 Wn.2d 460, 479.

⁶⁷⁰ *Ibid* 478 and Footnote 139.

⁶⁷¹ Elizabeth G Thornburg, 'The Curious Appellate Judge: Ethical Limits on Independent Research' (2008) 28(1) *Review of Litigation* 131, 133.

⁶⁷² Rachel C Lee, 'Ex Parte Blogging: The Legal Ethics of Supreme Court Advocacy in the Internet Era' (2009) 61(6) *Stanford Law Review* 1535, 1543.

⁶⁷³ Wikipedia is a website which 'allows virtually anyone to upload an article into what is essentially a free, online encyclopedia', as cited in *Campbell v Secretary of Health & Human Services* 69 Fed. Cl. 775, 781, 2006 US Claims LEXIS 45 (Fed.Cl., 2006) (Court of Federal Claims).

⁶⁷⁴ Lee F Peoples, 'The Citation of Wikipedia in Judicial Opinions' (2009) 12(1) *Yale Journal of Law and Technology* 1, 1.

⁶⁷⁵ 69 Fed. Cl. 775, 2006 US Claims LEXIS 45 (Fed.Cl., 2006) (Court of Federal Claims).

⁶⁷⁶ 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (U.S. Cal., 1993) (Supreme Court of the United States).

⁶⁷⁷ *Ibid*.

⁶⁷⁸ 69 Fed. Cl. 775, 2006 US Claims LEXIS 45 (Fed.Cl., 2006) (Court of Federal Claims).

While citing a website in a judicial opinion is not analytically identical to basing an expert opinion on such a source ..., the frequent citation of Wikipedia at least suggests that many courts do not consider it to be inherently unreliable. In fact, a recent and highly-publicized analysis in the magazine *Nature* found that the error rate of Wikipedia entries was not significantly greater than in those of the *Encyclopaedia Britannica*.⁶⁷⁹

As learned from the above cases, there is no hard and fast rule to answer the questions of admissibility of online health materials and the weight a court would assign to them. To face the different approaches of the American courts in different levels, Peoples has suggested a set of best practices for judges when they are referred to Internet sources such as Wikipedia.⁶⁸⁰

It is submitted that if all courts would allow admission of health information culled from the Internet and assign significant weight to those online materials, the judicial ruling might change the duty of health practitioners. When such change occurred, in order to catch up with medical developments so as to meet the legal requirement for exercising a reasonable standard of care for patients, the practitioners would need to ensure an effective mechanism to capture medical developments as fast as the speed of their being uploaded onto the Internet. As Gilmour has put it, health practitioners have to take greater care and attain more skills before they will be regarded as a 'normal, prudent practitioner'.⁶⁸¹ In reality, however, it is difficult for health practitioners to catch up with such fast changing 'contemporary' standards of care in the era of the Internet. In addition to the traditional continuous professional development in their own fields, Sokol and Molzen suggested that if health practitioners wish to meet their duty to exercise care and diligence in healing a patient, they must acquire knowledge from multiple sources, get acquainted with new medical devices, and become proficient in the use of information management tools which help patient monitoring and consultations.⁶⁸² Kuszler also alerted that in the future, when telemedicine technology is available to

⁶⁷⁹ 475 F. Supp. 2d 357, 361-362 (S.D.N.Y., 2007) (District Court of New York).

⁶⁸⁰ Peoples (n 674) 28-44.

⁶⁸¹ Gilmour (1994) (n 480) 190.

⁶⁸² Sokol and Molzen (n 619) 480.

facilitate a subspecialty consultation or definitive reading of a complex image or data set, failure to do so may result in a breach of the standard of care.⁶⁸³

5.4.2 The Health Practitioner's Status

The degree of care needed to satisfy the standard of care will vary according to the circumstances. The care expected of health practitioners will depend on what they have held themselves out as competent to do. It has been ruled in the UK that a practitioner's standard of care should be judged by the post he occupied at the time of the alleged clinical negligence, rather than by his or her personal experience. In *Wilsher v Essex Area Health Authority*⁶⁸⁴ a senior doctor failed to spot a junior's mistake and repeated his wrong insertion of a catheter into a vein of an infant patient instead of an artery and too much oxygen was delivered to the patient. As the junior doctor had checked with the senior, the Court of Appeal held that the junior was not negligent. Rather, the court found the senior doctor negligent and the health authority was vicariously liable. Mustill LJ said, 'the standard is not just that of the averagely competent and well-informed junior houseman (or whatever the position of the doctor) but of such a person who fills a post in a unit offering a highly specialized service.'⁶⁸⁵

Lack of experience is not a good defence in court.⁶⁸⁶ Technical readiness of health practitioners such as information and computer skills has a bearing on whether they exercise a reasonable standard of care for patients in telemedicine. In 1998 the American College of Physicians-American Society of Internal Medicine conducted a survey with a total of 9,466 respondents on their computer use and needs of internists. It was found that less than 19% of respondents had partial or complete electronic clinical functions in their practical settings and less than 7% of them exchanged emails with their patients on a weekly or daily basis. The respondents reported their want to increase general computer skills and enhance knowledge of computer-based information sources for, among others, patient care, EHR systems,

⁶⁸³ Kuszler (n 5) 316.

⁶⁸⁴ [1987] QB 730, [1986] 3 All ER 801 (Court of Appeal).

⁶⁸⁵ Ibid 751.

⁶⁸⁶ Malcom Khan, Michelle Robson and Kristina Swift, *Clinical Negligence* (2nd edn, Cavendish Publishing, London 2002) 158.

and telemedicine.⁶⁸⁷ In 2008 another study in Australia revealed that the principal barriers deterring nurses from using information and computer technology in the workplace included work demands, access to computers and lack of support. Other factors included age and lack of interest. Among the barriers, age was positively correlated with their knowledge and confidence in the use of computers.⁶⁸⁸

In order to further nourish the growth of telemedicine and minimize the legal risks of health practitioners interested in practising telemedicine, barriers preventing the use of information and computer technologies in health care settings must be addressed. An approach is to start computer and technology training for medical students which are proved to help effective medical education.⁶⁸⁹ Another effective approach is to facilitate health practitioners to sharpen their technical skills in using telemedical equipment in a reasonable manner, failing which would make them liable for a patient's injury even when the equipment concerned is owned by a health institute.⁶⁹⁰ In *Mafhouz v Xanar*,⁶⁹¹ the Court of Appeal of Louisiana held that while the hospital had a responsibility to set up equipment, when a problem arose during surgery, the surgeon had a duty to stop the operation and correct the problem if possible. If a health practitioner fails to use a new technique or misreads patient data, information or image because of unfamiliarity of telemedical systems, he or she may be liable for misuse.⁶⁹² The liability for technology failure may also be shared among all parties involved. In *Anderson v Somberg*,⁶⁹³ a patient was injured during an operation when a surgical instrument broke off and became lodged in his spine. The Supreme Court of New Jersey upheld the judgment of the appellate court that at least one of the defendants (a doctor, a hospital, and two medical suppliers) who possessed superior knowledge of and control over the factors that brought about the patient's injury was liable for the injury. Organizational liability of health institutes

⁶⁸⁷ David Lacher, Elizabeth Nelson, Wayne Bylsma and Robert Spena, 'Computer Use and Needs of Internists: A Survey of Members of the American College of Physicians-American Society of Internal Medicine' (2000) American Medical Informatics Association 453, 455.

⁶⁸⁸ Robert Eley, Tony Fallon, Jeffrey Soar, Elizabeth Buikstra and Desley Hegney, 'Barriers to use of information and computer technology by Australia's nurses: a national survey' (2009) 18(8) Journal of Clinical Nursing 1151.

⁶⁸⁹ Ibrahim Mansoor, 'Computer Skills Among Medical Learners: A Survey at King Abul Aziz University, Jeddah' (2002) 14(3) Journal of Ayub Medical College
<<http://www.ayubmed.edu.pk/JAMC/PAST/14-3/IbrahimMansoor.htm>> accessed 4 June 2012.

⁶⁹⁰ Kuszler (n 5) 317.

⁶⁹¹ 646 So. 2d 1152, 94-305 (La.App. 3 Cir. 11/16/94) (La.App. 3 Cir., 1994) (Court of Appeal of Louisiana, Third Circuit).

⁶⁹² Kuszler (n 5) 318.

⁶⁹³ 67 N.J. 291, 338 A.2d 1 (N.J. 1975) (Supreme Court of New Jersey).

and other technical failures in telemedicine such as malfunctioning of a satellite connection which disrupts a telemedical practice and results in patient's injury will be discussed in Chapter 7.

5.4.3 The Health Practitioner's Specialty of Practice

A health practitioner's standard of skill and care is to be judged by that of the ordinary practitioners practising within the same specialty and a defendant practitioner need not have the same standard as the most qualified or experienced specialists.⁶⁹⁴ In the UK, the House of Lords in *Whitehouse v Jordan*⁶⁹⁵ set out a test that a clinical error is negligent if a reasonably competent specialist having the standard and type of skill that the defendant held himself out as having, and acting with ordinary care, would not have committed the defendant's act or omission. If that specialist, acting with ordinary care, might have made the defendant's error, then the defendant is not negligent. Differences in medical opinions will not necessarily lead to medical negligence. The House of Lords in *Maynard v West Midlands Regional Health Authority*⁶⁹⁶ ruled that there is room for differences of opinion and practice in the medical profession and any preference of a court for a school of thought as opposed to another does not provide a basis for a conclusion of negligence. Similarly in *Gordon v Wilson*,⁶⁹⁷ Lord Penrose sitting on the Court of Session⁶⁹⁸ ruled that when there are two bodies of responsible opinion it is not an issue for the court to resolve by preference of one body as against the other.

In the US, health practitioners' standards of care vary from state to state but it typically comprises three components, namely professional, geographic, and standards existing at the time of the allegedly negligent event.⁶⁹⁹ In brief, a professional standard of care refers to the standard of care of a health practitioner expected in a specific health care profession and specialty defined within a specified geographic area or type of area at the time the alleged medical malpractice

⁶⁹⁴ Dunn (ed) (2010) (n 415) 11.

⁶⁹⁵ [1981] 1 WLR 246, [1981] 1 All ER 267 (House of Lords) (Lord Edmund-Davies, Lord Fraser of Tullybelton and Lord Russell of Killowen).

⁶⁹⁶ [1984] 1 WLR 634, [1985] 1 All ER 635 (House of Lords).

⁶⁹⁷ 1992 SLT 849, [1992] 3 Med LR 401 (Court of Session (Outer House)).

⁶⁹⁸ The supreme civil court of Scotland.

⁶⁹⁹ Joseph H King, 'The Common Knowledge Exception to the Expert Testimony Requirements for Establishing the Standard of Care in Medical Malpractice' (2007) 59(1) Alabama Law Review 51, 57-59.

occurred.⁷⁰⁰ In order to establish that the defendant's practice was substandard, expert testimony is always required. In *Johnson v Vaughn*,⁷⁰¹ the Court of Appeals of Kentucky held that in a medical negligence case, the claimant has the burden of proving negligence. That must be established by 'medical or expert testimony unless the negligence and injurious results are so apparent that laymen with a general knowledge would have no difficulty in recognizing it'. In *Hamby v University of Kentucky Medical Center*,⁷⁰² Howerton J in the same court added, 'in medical malpractice cases, expert testimony is always used to show the standard of care for a particular type of practice and procedure. The standard of care for physicians and surgeons is established by the medical profession itself.' In the context of geographic and time differences, the statutory requirements in the US for who could act as an expert in court vary from state to state, and may change from time to time. For example, the Michigan law has set out its statutory requirements that in an alleged clinical negligence claim, a health professional entitled to give expert testimony on the appropriate standard of practice or care must be licensed, specialize at the time of the occurrence in the same specialty as the defendant, and be board certified in that specialty; also, during the year immediately preceding the date of the occurrence of the adverse event, this professional must have devoted a majority of his or her professional time to either the active clinical practice of the same health profession as the licensed defendant, or the instruction of students in an accredited health entity or programme in the same health profession, or both. In case the defendant held himself or herself out as a specialist, the expert is required not only to be in the active practice of the same health profession but in the active clinical practice of the same specialty as the defendant is licensed. The court has to evaluate, at a minimum, the educational and professional training of the expert witness, his or her area of specialization, the length of time engaged in active practice or instruction, and the relevance of the expert witness's testimony.⁷⁰³

5.4.4 New Concerns about the Standard of Care Arising from Telemedicine

Telemedicine raises new concerns about the technical standard of care. For example, the use of compressed videos in telemedicine has raised a new concern

⁷⁰⁰ Ibid.

⁷⁰¹ 370 S.W.2d 591, 596 (Ky., 1963) (Court of Appeals of Kentucky).

⁷⁰² 844 S.W.2d 431, 434 (Ky.App., 1992) (Court of Appeals of Kentucky).

⁷⁰³ United States, Michigan Compiled Laws Annotated §600.2169.

about whether a tele-doctor has diagnosed with ‘less than complete information’, as repetitious information is eliminated in the process of data conversion from analogue to digital formats during telemedicine.⁷⁰⁴ In *Brown v University of Alberta Hospital*, Marceau J in the Alberta Court of Queen’s Bench said, ‘Common sense, hospital policy and precise legislation mandate that the medical professionals go beyond pure diagnosis ...’⁷⁰⁵ Telemedicine has motivated, if not forced, health practitioners to go even further. As a result of the new concerns about the standard of care of telemedicine, some new codes of practice and new legislation are made. For instance, the American College of Radiology has issued a set of written telemedicine standards to facilitate the electronic practice of medical imaging, though it has cautioned against the use of these standards in litigation where a practitioner’s clinical decisions are queried.⁷⁰⁶ In California, the Telemedicine Development Act 1996 required patients to sign a separate, telemedicine-specific consent form not related to any law of privacy, security or patient informed consent on the state or federal level, and such a consent form was considered ‘redundant, inefficient, and burdensome’ and created stigma for patients’ use of telemedicine as traditional health services do not require the same from patients.⁷⁰⁷ In replacing the 1996 Act, the new Telehealth Advancement Act 2011 provides parity between telemedical practices and traditional in-person practices and requires that patients’ verbal consent prior to the delivery of telehealth should be obtained for the use of telemedicine and documented in patients’ medical records.⁷⁰⁸

Apart from the technical concerns about, for instance, the use of compressed videos and medical imaging and how to obtain patient consent, it is also a concern about the personal standard of care of health practitioners who practise telemedicine. Health practitioners have an obligation to use skill, care, and knowledge that has been currently adopted by the profession in the diagnosis and

⁷⁰⁴ Joseph N Gitlin, ‘Teleradiology’ in Bashshur, Sanders and Shannon (eds) (1997) (n 89) 170.

⁷⁰⁵ (1997), 33 CCLT (2d) 113, 48 Alta LR (3d) 1, 197 AR 237, 145 DLR (4th) 63, [1997] 4 WWR 645, 4 WWR 645, [1997] AJ No. 298 (Alberta Court of Queen’s Bench), [200] (per Marceau J).

⁷⁰⁶ American College of Radiology, *ACR Technical Standard for Electronic Practice of Medical Imaging* (Amended 2009 (Resolution 11))

<http://www.acr.org/secondarymainmenucategories/quality_safety/guidelines/med_phys/electronic_practice.aspx> accessed 12 April 2012, 1.

⁷⁰⁷ Center for Connected Health Policy, *Advancing California’s Leadership in Telehealth Policy: A Telehealth Model Statute & Other Policy Recommendations* (February 2011) 12.

⁷⁰⁸ United States, California Business and Professions Code §2290.5(b).

treatment of a patient,⁷⁰⁹ and the standard of care often follows the development of medical information and techniques being introduced in different specialties.⁷¹⁰ In the US, one of the questions before the court in *Darling v Charleston Community Memorial Hospital*⁷¹¹ was the defendant hospital's liability for failing to require staff members to keep abreast of modern techniques in medical developments. The Supreme Court of Illinois affirmed the appellate court's judgment that the defendant hospital was liable for the negligence of its on-call doctor who had not read a book on orthopaedics in at least ten years but set the broken leg of the claimant's son in an emergency room, without consulting a specialist. The leg eventually had to be amputated because of complications. Likewise in the UK, it was held in *Gascoigne v Ian Sheridan & Co*⁷¹² that a gynaecologist had to keep updated with developments in the mainstream practices but would not be required to be aware of the content of more obscure journals. Donaldson said that when new clinical tools are proved to be responsive, useful, and effective, in addition to providing better medical care for patients, their use may become a new standard of care that defines good medical care.⁷¹³ Professional training is therefore important. A recent survey in Uganda found that the top two respondents' concerns which affect the development of telemedicine in this developing country were the lack of telemedicine-skilled staff in their hospitals and the lack of training support for staff in telemedicine.⁷¹⁴ Another online survey in France⁷¹⁵ involving 721 general practitioners in 2009 showed that 84.6% of the respondents used the 'Web/Internet' to seek information in clinical practice, followed by 'books and printed journals' (86.3%) and 'continuing medical education, congress and seminar' (85.6%), but among these respondents, 62.5% received no Internet training for clinical practice. Interestingly, 76.5% self-assessed their competencies in using the Internet for information seeking as 'rather good' or 'good'. As regards obstacles to the use of Internet for patient care information, about

⁷⁰⁹ Angela R Holder, 'Failure to "Keep Up" as Negligence' (1973) 224(10) Journal of the American Medical Association 1461, 1461.

⁷¹⁰ Sokol and Molzen (n 619) 471.

⁷¹¹ 33 Ill. 2d 326, 211 N.E.2d 253 (Ill. 1965) (Supreme Court of Illinois).

⁷¹² [1994] 5 Med LR 437.

⁷¹³ Molla S Donaldson, 'Taking Stock of Health-Related Quality-of-Life Measurement in Oncology Practice in the United States' (2004) 33 Journal of the National Cancer Institute Monographs 155, 160.

⁷¹⁴ Stephen R Isabalija, Kituyi G Mayoka, Agnes S Rwashana and Victor W Mbarika, 'Factors Affecting Adoption, Implementation and Sustainability of Telemedicine Information Systems in Uganda' (2011) 5(2) Journal of Health Informatics in Developing Countries 299, 309.

⁷¹⁵ Erik Bernard, Michel Arnould, Oliver Saint-Lary, Didier Duhot and Gilles Hebbrecht, 'Internet use for information seeking in clinical practice: A cross-sectional survey among French general practitioners' (2012) 81(7) International Journal of Medical Informatics 493.

half of them gave a response of ‘too much information to scan’ (47.7%) and ‘lack of time’ (47.0%). They also pointed out that language has been a barrier (34.1%). If the respondent doctors in this survey were asked to practise telemedicine, it would not be difficult to identify a skill gap between competent telemedical practices against general practices. Training quality is also crucial. In the case of telesurgery, McLean queried whether a 3-day training course could be sufficient for a surgeon to acquire adequate foundation skills, given the fact that surgeons are not trained experts in engineering and would not be able to identify defects that are easily spotted by an engineer.⁷¹⁶

There are also concerns about the organizational standard of care of health institutes, as telemedicine may elevate the current standard of care to an extent that it will be sub-standard if a health institute does not provide telemedical services.⁷¹⁷ New technological tools disseminate the latest medical studies quickly and reduce the lag time,⁷¹⁸ which may accelerate the speed of an innovative technology to replace the existing practices and become a new and accepted standard.⁷¹⁹ In *Washington v Washington Hospital Center*⁷²⁰ in the US, a patient underwent elective surgery in late 1987 and suffered permanent brain injury owing to allegedly improper administration of anaesthesia. The claimant alleged that the defendant hospital had been negligent as it deviated from the standard of care by failing to provide the anaesthesiologists with a carbon dioxide monitor which allows early detection of insufficient oxygen for the surgery.⁷²¹ In fact, such monitors were innovative at that time. It was only published in the Journal of American Medical Association in August 1986 that the monitors had been in use at the Harvard Medical School in 1985 and the use of such monitors to monitor carbon dioxide was ‘an emerging standard and [was] strongly preferred.’⁷²² It was revealed in court that at least four other teaching hospitals in the US had used the monitors by that time.⁷²³ The District of Columbia Court of Appeals ruled that ‘[with] other evidence ..., in combination with [the testimony of the claimant’s expert], a reasonable juror could fairly conclude that [carbon dioxide] monitors were

⁷¹⁶ Thomas R McLean, ‘Cybersurgery – An Argument for Enterprise Liability’ (2002) 23(2) The Journal of Legal Medicine 167, 185.

⁷¹⁷ Kuszler (n 5) 316.

⁷¹⁸ Sokol and Molzen (n 619) 471.

⁷¹⁹ Kuszler (n 5) 316.

⁷²⁰ 579 A.2d 177 (D.C., 1990) (District of Columbia Court of Appeals).

⁷²¹ Ibid 180.

⁷²² Ibid 182.

⁷²³ Ibid 183.

required of prudent hospitals similar to [the defendant hospital] in late 1987.’⁷²⁴ Hodge and colleagues queried how to resolve the liability issues when a treating doctor fails to use telemedicine when it is needed or fails to use it properly.⁷²⁵

5.4.4.1 Standard of Care of Alternative Medicine: A Hint to Telemedicine?

Alternative medicine may give a hint to the query of Hodges et al. Telemedicine has changed legal considerations behind medical malpractice claims. In the absence of physical contact with patients, what standard of care should be applied to a doctor practising telemedicine for a patient located in another site?⁷²⁶ In the UK, the court may take a different position when it considers the standard of care involving a practitioner of alternative medicine and may not follow exactly the same ruling of *Bolitho* in conventional medicine.⁷²⁷ In *Shakoor v Situ*,⁷²⁸ a patient died after receiving several doses of herbal treatment prescribed by the defendant (a Chinese medicine practitioner) alongside orthodox medical treatment. The legal question for the court was to determine whether the defendant was to be judged by the standards of orthodox medical practitioners in the UK or the ‘reasonably careful practitioner’ of Chinese medicine. It was held that the defendant could not be judged by the standards of medical men who practised in an equivalent position in orthodox medicine since he was not holding himself out as a practitioner of such medicine and his patient had chosen to reject the orthodox approach. It would not be sufficient, either, to judge him by the standard of ordinary practitioners skilled in his particular ‘art’ (Chinese medicine). It would be necessary for the court to have regard to the fact that the defendant was practising Chinese medicine alongside orthodox medicine and consider whether the defendant’s standard of care had taken account of the implications of that fact.

To apply *Shakoor*⁷²⁹ in telemedicine settings, health practitioners in telemedicine may be subject to a set of standards of care different from the ordinary sense of a reasonable standard of care of orthodox health practitioners at common law.

⁷²⁴ Ibid 183.

⁷²⁵ Hodge, Gostin and Jacobson (n 572) 1469.

⁷²⁶ Roy Miller, ‘The New House Call; Telemedicine Puts a Different Image on Seeing the Doctor’ *Dallas Morning News* (Dallas, Texas of the United States, 20 December 1993), as cited in Ibid 33, Footnote 44.

⁷²⁷ Dunn (ed) (2010) (n 415) 12.

⁷²⁸ [2001] 1 WLR 410, [2000] 4 All ER 181 (High Court Queen’s Bench).

⁷²⁹ Ibid.

Magenau argued that applying the ordinary standard of care to a telemedicine doctor has effectively applied a higher standard to that doctor, as the virtual environment and the lack of physical contact have actually limited the doctor's practices in some circumstances.⁷³⁰ The telemedicine doctor may be under an additional duty to arrange the patient to undergo physical examination by himself or herself or another health practitioner to help correct diagnosis if the situation is deemed appropriate. Also, as explained before, health practitioners in telemedicine are expected to be acquainted with reasonable computer literacy skills. The previously mentioned French online survey⁷³¹ involving 721 general practitioners showed that 62.5% of the respondents received no Internet training for clinical practice, though 76.5% self-assessed their competencies to using the Internet for information seeking as 'rather good' or 'good'. If they were to practise telemedicine, they might be subject to enhanced medico-legal risks. To follow *Bolam v Friern Hospital Management Committee*,⁷³² computer skills may be considered special skills in court for health practitioners who have held themselves out as telemedicine specialists. One of those computer skills is to manage health information. Health practitioners have to learn how to master the development of IT for patients' benefits; otherwise, patients may lose confidence in their health practitioners if they find that the practitioners are not competent to use real-time health information.⁷³³ *Whitehouse v Jordan*⁷³⁴ in the UK may be applied in a similar fashion in cyberspace that a defendant telemedicine doctor is negligent if he or she has committed a clinical error in a cyber setting, which a reasonably competent telemedicine specialist having the standard and type of skill that the defendant held himself or herself out as having, and acting with ordinary care, would not have committed the error. The World Medical Association has made it loud and clear that training in telemedicine should be part of both basic and continued medical education for all physicians and other health practitioners interested in telemedicine.⁷³⁵

⁷³⁰ Magenau (n 499) 33.

⁷³¹ Bernard and others (n 715) 496.

⁷³² [1957] 1 WLR 582, 586, [1957] 2 All ER 118 (High Court Queen's Bench).

⁷³³ David Blumenthal, 'Doctors in a wired world: can professionalism survive connectivity?' (2002) 80(3) *The Milbank Quarterly* 525, 539.

⁷³⁴ [1981] 1 WLR 246, [1981] 1 All ER 267 (House of Lords).

⁷³⁵ World Medical Association, World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine (adopted by the 51st World Medical Association General Assembly, Tel Aviv, Israel, October 1999) §26.

5.4.5 Standards in the Home and the Remote Territories – Credentialing and Licensing

5.4.5.1 The United States

Health practitioners practising telemedicine have to abide by the laws of both the home and the remote territories. In the US, despite the historical co-existence of two sets of standards of care, the trend in the past decade has been moving from community standards towards a uniform and national standard for specialists.⁷³⁶ As early as 1975, Levin J in the Court of Appeals of Maryland in *Shilkret v Annapolis Emergency Hospital Association* said, ‘In sum, the traditional locality rules no longer fit the present-day medical malpractice case.’⁷³⁷ In *Hall v Hilbun* in 1985, Robertson J sitting on the Supreme Court of Mississippi said, ‘Because of differences in facilities, equipment, etc., what a physician may reasonably be expected to do in the treatment of a patient in [a rural county] may vary from what a physician in [a large city] may be able to do. ... In contradistinction, objectively reasonable expectations regarding the physician’s knowledge, skill, capacity for sound medical judgment and general competence are, consistent with his field of practice and the facts and circumstances in which the patient may be found, *the same everywhere* (emphasis added).’⁷³⁸ In *Sheeley v Memorial Hospital* in 1998, Goldberg J in the Supreme Court of Rhode Island said, ‘Accordingly we join the growing number of jurisdictions that have repudiated the “same or similar” communities test in favor of a national standard and hold that a physician is under a duty to use the degree of care and skill that is expected of a reasonably competent practitioner in the same class to which he or she belongs, acting in the same or similar circumstances.’⁷³⁹

This ‘nationalisation’ process of the standard of care in the US, albeit slow, has a positive impact on the standard of care in telemedicine. One of the characteristics of telemedicine is ‘health care without borders’.⁷⁴⁰ In theory, it overcomes geographic distance and facilitates patients in remote or under-developed areas to receive treatment of a comparable quality to their counterparts in developed

⁷³⁶ Kuszler (n 5) 315.

⁷³⁷ 276 Md. 187, 199, 349 A.2d 245, 252 (Md. 1975) (Court of Appeals of Maryland).

⁷³⁸ 466 So.2d 856, 872 (Miss., 1985) (Supreme Court of Mississippi).

⁷³⁹ 710 A.2d 161, 167 (R.I., 1998) (Supreme Court of Rhode Island) (Goldberg J).

⁷⁴⁰ Perednia (n 248) [1].

districts or countries. In practice, when different states or countries have different standards of care in legal terms, it hinders the growth of telemedicine, mostly through two different processes, namely licensing requirements and credentialing to determine whether a health practitioner possesses appropriate qualifications to provide services. This geographic concept of the US standard of care stands as one of the major barriers impacting telemedicine, which has created ‘the first and most obvious stumbling block’⁷⁴¹ to the development of telemedicine. Caryl said that the licensing system of different American states is the first line of assurance for quality medical care and the medical malpractice system only serves as the second line of protection for patients.⁷⁴² While a state licensing system assures the quality of health services for citizens in a state, it deters the development of telemedicine. Because of different standards of care in various states of the US, health practitioners have to comply with different state licensure requirements when they practise telemedicine. Problems arise when health practitioners provide services through telemedicine in jurisdictions where they are not properly licensed.⁷⁴³ The fear of malpractice liability discourages health practitioners from providing telemedical services to remote areas and it hinders the enhancement of healthcare standards in rural districts. If telemedicine is readily available, rural health practitioners will have greater access to other practitioners to verify a diagnosis or treatment, thus improving the quality of health service delivery for citizens.⁷⁴⁴ Rowthorn and Hoffmann commented that the current multiple-state licensing system would make health practitioners feel burdened due to the time and costs involved in applying for multiple licences.⁷⁴⁵ To tackle this issue, the National Council of State Boards of Nursing, for instance, studied a multi-state licensure system to facilitate tele-nursing across state lines.⁷⁴⁶ The Nurse Licensure Compact, which provides mutual recognition of nursing licensure between different states, is the result of this effort.⁷⁴⁷ The Federation of State Medical Boards of the US also accepted in 1996 ‘A Model Act to Regulate the Practice of Medicine Across State Lines’, which recommended states create a special licence for doctors

⁷⁴¹ Delbert D Smith, ‘Distant Doctors’ (1998) 22(5) *Satellite Communications* 32, 34-35.

⁷⁴² Caryl (n 130) 191.

⁷⁴³ Delbert D Smith (n 741) 35.

⁷⁴⁴ Caryl (n 130) 193.

⁷⁴⁵ Virginia Rowthorn and Diane Hoffmann, ‘Legal Impediments to the Diffusion of Telemedicine’ (2011) 14(1) *Journal of Health Care Law & Policy* 1, 10.

⁷⁴⁶ Roy L Simpson, ‘State Regulation in a World of “Boundary-less” Technology’ (1997) 28(2) *Nursing Management* 22.

⁷⁴⁷ Becker (n 607) 958-962.

who engage in the practice of telemedicine across state lines and further recommended that in cases of emergency and informal doctor-doctor consultations without financial compensation to an advising doctor, the out-of-state doctor should be exempt from the need for a licence in the patient's state.⁷⁴⁸ States including Alabama, Minnesota, Montana, Nevada, New Mexico, Ohio, Oregon, Tennessee, and Texas have adopted this special-licence system.⁷⁴⁹ In Oregon, for example, the Medical Practice Act requires that a person may not engage in the practice of 'medicine across state lines'⁷⁵⁰ unless he or she is licensed,⁷⁵¹ which requires that a doctor must hold a full and unrestricted licence to practise medicine in any other state before he or she will be licensed to practise telemedicine.⁷⁵² This out-of-state doctor has the same duties and responsibilities including, for example, establishment of a physician-patient relationship, making a clinical judgement based on objective criteria, and treating patients in their best interest, etc. and is subject to the same penalties and sanctions as any other doctors licensed under the Act. A licence to practise telemedicine is not necessary in emergency,⁷⁵³ in situations where an out-of-state doctor consults a doctor in Oregon,⁷⁵⁴ or where the outside doctor has a doctor-patient relationship with a patient who is located temporarily in Oregon and requires that out-of-state doctor's direct medical treatment.⁷⁵⁵ The out-of-state doctor so licensed must not, among others, act as a dispensing physician⁷⁵⁶ and must comply with all applicable laws, rules and regulations in Oregon governing the maintenance of medical records and patient confidentiality requirements.⁷⁵⁷ In Ohio, each doctor has to take an examination in order to be licensed to practise medicine⁷⁵⁸ and pays examination fees.⁷⁵⁹ However, this special-licence system seems not to be welcomed by American doctors. Up to June 2011, no special inter-state licence was issued.⁷⁶⁰

⁷⁴⁸ Federation of State Medical Boards of the United States (1996) (n 39).

⁷⁴⁹ American Medical Association, *Report of the Council on Medical Education – Telemedicine and Medical Licensure (CME Report 6-A-10)*, 2 <<http://www.ama-assn.org/resources/doc/council-on-med-ed/cme-rep6-a10.pdf>> accessed 18 May 2012.

⁷⁵⁰ United States, Oregon Revised Statutes, Chapter 677 Regulation of Medicine, Podiatry and Acupuncture, Medical Practice Act §677.135.

⁷⁵¹ Ibid §677.137.

⁷⁵² Ibid §677.139(1).

⁷⁵³ Ibid §677.060(3).

⁷⁵⁴ Ibid §677.137(3).

⁷⁵⁵ Ibid §677.137(4).

⁷⁵⁶ Ibid §677.010(5) and (6).

⁷⁵⁷ Ibid §677.141(3).

⁷⁵⁸ United States, Ohio Revised Code, Chapter 4731 Physicians – Limited Practitioners §4731.13.

⁷⁵⁹ Ibid §4731.12.

⁷⁶⁰ Nakajima, 'Cross-Border Medical Care and Telemedicine' (2012) (n 139) 51.

Other states in the US have different telemedicine licensing requirements. In Guam, one of the exceptions to the Physicians Practice Act is provided for doctors who practise telemedicine, and a telemedicine licence is not required.⁷⁶¹ The Act states that a licensed doctor who resides outside of Guam within a State, Federal jurisdiction or country is not subject to Guam medical licensure requirements where he or she is providing consultation to a Guam licensed doctor through the use of telemedicine technology if the non-resident licensed consulting doctor does not operate a clinical practice or an office on Guam, does not provide any written or documented final medical opinion on diagnosis or treatment directly to a patient on Guam, and does not render any treatment to any patient there.⁷⁶² This consulting doctor may render care and provide final diagnostic and treatment decisions or recommendation without an active Guam licence if he or she is to either act as a receiving doctor for the patient in his or her own jurisdiction, or act jointly and directly with the attending doctor of the patient on Guam.⁷⁶³ This consulting doctor has to comply with all local and federal laws with regard to patient confidentiality.⁷⁶⁴ In California, subject to a few exceptions, the Business and Professions Code does not require out-of-state doctors to get any licence before having a telemedical consultation with in-state doctors.⁷⁶⁵

In contrast to a special-licence system, Venable has advocated the adoption of a national standard of care for telemedicine practitioners and liberalization of its licensure standards.⁷⁶⁶ In theory a unified licensing system will nourish the further growth of telemedicine. In practice it is an extremely complicated task technically and politically. In the technical perspective, each country has its own system to license different types of health practitioners and has had its own medical customs, not to mention the possible co-existence of some categories of alternative medicine with main-stream medicine. In the political sense, protectionism plays a role in this unification process. In the US, state medical societies worried about out-of-state doctors poached their patients and lobbied the regulation of telemedicine.⁷⁶⁷ The

⁷⁶¹ United States, Guam Code Annotated, Title 10 Health and Safety, Division 1 Public Health, Chapter 12 Medical Practices (Part 1), Art 2 Physicians Practice Act, §12202(b)(8).

⁷⁶² Ibid §12202(b)(8)(i) – (iii).

⁷⁶³ Ibid §12202(b)(8)(iv) – (v).

⁷⁶⁴ Ibid §12202(b)(8)(vi).

⁷⁶⁵ United States, California Business and Professions Code §2060.

⁷⁶⁶ Shannon S Venable, 'A Call to Action: Georgia Must Adopt New Standard of Care, Licensure, Reimbursement, and Privacy Laws for Telemedicine' (2005) 54 Emory Law Journal 1183, 1184.

⁷⁶⁷ Richard Haugh, 'Static from states' (2001) 75(7) Hospitals & Health Networks 20, 20.

Federal Trade Commission and the Department of Justice said, 'The practice of telemedicine has ... crystallized tensions between the states' role in ensuring patients have access to quality care and the anticompetitive effects of protecting in-state physicians from out-of-state competition.'⁷⁶⁸ Also, American doctors with high overhead costs due to medical malpractice insurance may not compete with their Canadian counterparts with minimal overheads,⁷⁶⁹ and they have to urge the US governments not to open the market so as to protect their interests. In both the UK and India, protectionism and pressures from unions and professional bodies also act as the key barriers to the development of telemedicine services.⁷⁷⁰ Japan is no exception. The Japan Medical Association raised an objection to employment of foreign licensed doctors.⁷⁷¹ Nevertheless, to have technical and political difficulties does not necessarily mean a reform is not viable. Precedent cases existed in the US where doctors serving in the military, the Department of Veterans Affairs, the Indian Health Service, and the Public Health Service were granted national licences.⁷⁷²

Ameringer has also urged a change to the existing American state-based licensing approach to facilitate the growth of telemedicine and he calls for a uniform approach to interstate medical practice instead of a national licence for the practice of telemedicine, out of foreseeable practical difficulties such as complex administration of different state medical boards and the problems of choice of law.⁷⁷³ To alleviate the restriction further, the Committee on Medicine and Law of the International Bar Association Section on Legal Practice in the US has proposed that each country facilitate a reasonable chance for overseas health practitioners to attain full and unrestricted licensure and that practitioners apply for authorization to an internationally recognized organization whose standards would be recognized by the country concerned.⁷⁷⁴ It can be imagined that such an ideal international licensing system would be more diverse and controversial than the interstate licensing systems

⁷⁶⁸ United States, Federal Trade Commission and Department of Justice (n 380) Chapter 2, 32 <<http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>> accessed 21 February 2012.

⁷⁶⁹ C R Ewell, 'Telemedicine: Overcoming Obstacles on the Road to Global Health Care' (2003) 12(winter) *International Trade Law Journal* 68, 75.

⁷⁷⁰ Melisa Martínez Álvarez, Rupa Chanda and Richard D Smith, 'How is Telemedicine perceived? A qualitative study of perspectives from the UK and India' (2011) 7(17) *Globalization and Health* 1, 5.

⁷⁷¹ Nakajima, 'Cross-Border Medical Care and Telemedicine' (2012) (n 139) 49.

⁷⁷² Sanders and Bashshur (1995) (n 32) 118.

⁷⁷³ Carl F Ameringer, 'State-based Licensure of Telemedicine: The Need for Uniformity but Not a National Scheme' (2011) 14(1) *Journal of Health Care Law & Policy* 55.

⁷⁷⁴ Schanz 1991, as cited in Maheu, Whitten and Allen (n 22) 178.

within the US,⁷⁷⁵ and the viability of this system will likely be subject to serious challenges in both technical and political senses.

5.4.5.2 The European Union

The EU has tried to facilitate the growth of telemedicine in Europe through mutual recognition of professional qualifications,⁷⁷⁶ allowing health practitioners the freedom to serve patients across different member states. The EU Directive 2005/36/EC sets out the criteria for the mutual recognition of professional qualifications and guarantees nationals of a member state who have acquired their professional qualifications to have access to the same profession and pursue it in another member state with the same rights as nationals.⁷⁷⁷ The EU also adopted a Communication entitled ‘Telemedicine for the Benefit of Patients, Healthcare Systems and Society’ at the end of 2008 to support the wider deployment of telemedicine by focusing on three strategic directions: (a) Building confidence in and acceptance of telemedicine services, (b) bringing legal clarity, and (c) solving technical issues and facilitating market development.⁷⁷⁸ In particular, in the context of legal clarity, the EU considered, inter alia, licensing, accreditation and registration of telemedicine services and professionals a major challenge for telemedicine⁷⁷⁹ and requested member states to have assessed and adapted their national regulations to address issues including accreditation and to facilitate wider access to telemedicine services by the end of 2011.⁷⁸⁰

The US and the EU have given illustrations on how different legal requirements in different territories have impacted on telemedicine. To complicate the matter further, if in a virtual encounter between a patient and a health practitioner, one side runs a common law system and the other side practises a civil law system, just like the cross-border telemedicine practices between Hong Kong and China,

⁷⁷⁵ Delbert D Smith (n 741) 34-35.

⁷⁷⁶ European Union, Council Directive 81/1057/EEC of 14 December 1981 supplementing Directives 75/362/EEC, 77/452/EEC, 78/686/EEC and 78/1026/EEC concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of doctors, nurses responsible for general care, dental practitioners and veterinary surgeons respectively, with regard to acquired rights.

⁷⁷⁷ European Union, Council Directive 2005/36/EC of 7 September 2005 on the recognition of professional qualifications, Preamble [3].

⁷⁷⁸ European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on ‘Telemedicine for the Benefit of Patients, Healthcare Systems and Society’* (European Commission, Brussels, 2008, COM(2008)689 final) 6.

⁷⁷⁹ Ibid 8.

⁷⁸⁰ Ibid 11.

issues including but not limited to the choice of law, jurisdiction, recognition and enforcement have to be added to the list of legal considerations, on top of those within a federal system like the US or a political and economic entity like the EU. The case between Hong Kong and China will be addressed in Chapter 8.

5.5 Proof of Breach of the Duty of Care and Telemedicine

Liability will not follow a breach of the duty of care if the breach does not lead to any harm or injury.⁷⁸¹ A ‘victim’ has to suffer some sort of injury before he or she can bring an action against alleged clinical negligence. The claimant has the onus of proof to show on the balance of probabilities that the defendant health practitioner has breached the duty of care.⁷⁸² The maxim *res ipsa loquitur* bearing a meaning of ‘the thing speaks for itself’ allows the court to draw an inference that the defendant was negligent, based on the mere fact that an event occurred, without the benefit of having expert evidence confirming that the defendant’s standard of care fell below a reasonable standard.⁷⁸³ In the UK, Erle CJ in *Scott v The London and St. Katherine Docks Company* gave the following classic exposition of the maxim,

There must be reasonable evidence of negligence. But where the thing is shown to be under the management of the defendant or his servants, and the accident is such as in the ordinary course of things does not happen if those who have the management use proper care, it affords reasonable evidence, in the absence of explanation by the defendants, that the accident arose from want of care.⁷⁸⁴

If the term ‘the thing’ in the above quotation is replaced by the phrase ‘the treatment of the claimant’, it shows the apparent application of *res ipsa loquitur* to adverse medical events.⁷⁸⁵ *Ritchie v Chichester Health Authority*⁷⁸⁶ confirmed that the maxim was applicable to clinical negligence cases. *Res ipsa loquitur* may help a claimant in a clinical negligence case, where the claimant lacks medical knowledge and is not in a professional position to know what treatment was given or to establish

⁷⁸¹ Chew (n 446) 29 [2.95].

⁷⁸² Emily Jackson (n 325) 139.

⁷⁸³ Ibid 140.

⁷⁸⁴ (1865) 3 Hurl & C 596, 601, 159 ER 665, 667 (Court of Exchequer).

⁷⁸⁵ Powell, Stewart and Jackson (eds) (2007) (n 391) 931 [13-040].

⁷⁸⁶ [1994] 5 Med LR 187, 205 (High Court Queen’s Bench).

how the injury was caused by the defendant health practitioner.⁷⁸⁷ In accordance with this maxim, the legal burden of proof is shifted from a claimant to a defendant who cannot escape liability unless he or she calls evidence to rebut *res ipsa loquitur* by demonstrating to the court that he or she has exercised reasonable care or that there is a non-negligent alternative explanation to the claimant's injury.⁷⁸⁸

However, other cases in the common law jurisdictions had different views on this maxim. In the UK, Denning LJ in *Roe v Minister of Health* said, '[W]e should be doing a disservice to the community at large if we were to impose liability on hospitals and doctors for everything that happens to go wrong ... We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure.'⁷⁸⁹ Megaw LJ in the Court of Appeal in *Lloyde v West Midlands Gas Board*⁷⁹⁰ said, 'I doubt whether it is right to describe *res ipsa loquitur* as a "doctrine." I think that it is no more than an exotic, although convenient, phrase to describe what is in essence no more than a common sense approach, not limited by technical rules, to the assessment of the effect of evidence in certain circumstances.' The Court of Appeal in *Ratcliffe v Plymouth and Torbay Health Authority*⁷⁹¹ held that *res ipsa loquitur* could be applied only in simple medical negligence cases, e.g. a doctor's cutting off a wrong foot or leaving swab inside the body after an operation, but not in contested cases where expert evidence was required to buttress such an inference. Hobhouse LJ said, '*Res ipsa loquitur* is not a principle of law: it does not relate to, or raise, any presumption. It is merely a guide to help to identify where a *prima facie* case is being made out. Where expert and factual evidence has been called on both sides at a trial, its usefulness will normally have long since been exhausted.'⁷⁹² In Canada, Major J sitting on the Supreme Court of Canada in *Fontaine v Loewen Estate* said, 'It would appear that the law would be better served if the maxim [*of res ipsa loquitur*] was treated as expired and no longer used as a separate component in negligence actions.'⁷⁹³ A claimant has to adduce evidence to prove an allegation that a defendant health practitioner has breached the duty of care

⁷⁸⁷ Ibid 930-931 [13-039].

⁷⁸⁸ Dunn (ed) (2010) (n 415) 18.

⁷⁸⁹ [1954] 2 QB 66, 86-87, [1954] 2 All ER 131 (Court of Appeal).

⁷⁹⁰ [1971] 1 WLR 749, 755, [1971] 2 All ER 1240 (Court of Appeal).

⁷⁹¹ [1998] PIQR P170, [1998] Lloyd's Rep Med 162, (1998) 42 BMLR 64 (Court of Appeal).

⁷⁹² Ibid [1998] PIQR P170, P189-P190.

⁷⁹³ (1997), 156 DLR (4th) 577, 103 BCAC 118, 169 WAC 118, 223 NR 161, 46 BCLR (3d) 1, [1998] 1 SCR 424, [1998] 7 WWR 25, 34 MVR (3d) 165, 41 CCLT (2d) 36, [1997] SCJ No. 100, REJB 1998-05407, JE 98-715 (Supreme Court of Canada), [27].

and failed to meet the standard of care required in the specific circumstances, thus committing a negligent act.⁷⁹⁴ In Hong Kong, the Privy Council in *Ng Chun Pui v Lee Chuen Tat* held that it was misleading to talk of the burden of proof shifting to the defendant in a *res ipsa loquitur* situation.⁷⁹⁵ In Australia, the High Court in *Schellenberg v Tunnel Holdings Pty Ltd*⁷⁹⁶ held that *res ipsa loquitur* is merely descriptive of a method of reasoning by which, in appropriate cases, a prima facie case of negligence may be made out.

As telemedicine involves cross-border practices, it faces a difficulty in how to prove a breach of duty of care and whether *res ipsa loquitur* would be applied to shift the burden of proof from a claimant to a health practitioner practising telemedicine. In clinical negligence cases touching upon the arguments of *res ipsa loquitur*, it may not be easy to ascertain a court's position with this maxim, but, as Atiyah advocated,⁷⁹⁷ the view that *res ipsa loquitur* may not be used to determine whether there has been any breach of standard of care is now more prevalent, if not fully accepted without doubt.

5.6 Causation

5.6.1 Common Law

5.6.1.1 General Principles

It is trite law that 'the onus of proving causation lies on the pursuer or plaintiff'.⁷⁹⁸ However, as clinical negligence is a specialized area of tort and causation of a medical adverse event is a legal element difficult to prove, a lay person may find it difficult to establish negligence of a health practitioner because of the imbalance of expertise between the parties to the litigation.⁷⁹⁹ Another difficulty is due to the nature of these cases that there are usually two possible causes for adverse outcomes: the health practitioners' breach of the duty of care or the patients' pre-

⁷⁹⁴ Vivienne Harpwood, *Legal Issues in Obstetrics* (Darmouth Publishing, England 1996) 150.

⁷⁹⁵ [1988] 2 HKLR 425, [1988] RTR 298, (1988) 132 SJ 1244 (Privy Council).

⁷⁹⁶ [2000] HCA 18, (2000) 200 CLR 121, 74 ALJR 743, 170 ALR 594 (High Court of Australia).

⁷⁹⁷ P S Atiyah, 'Res Ipsa Loquitur in England and Australia' (1972) 35(4) The Modern Law Review 337.

⁷⁹⁸ *Wilsher v Essex Area Health Authority* [1988] AC 1074, [1988] 1 All ER 871 (House of Lords).

⁷⁹⁹ United Kingdom, Nuffield Council on Bioethics, *Critical care decisions in fetal and neonatal medicine: ethical issues*. (Nuffield Council on Bioethics, London, United Kingdom 2006) 106, Footnote 62.

existing medical conditions.⁸⁰⁰ The Chief Medical Officer for England said that it is ‘a lottery who can and who cannot prove “negligence”.’⁸⁰¹ Lord Woolf also attributed the excessive legal litigation costs in clinical negligence cases in the UK to the difficulty of proving both causation and negligence.⁸⁰²

Generally speaking, at common law, to decide whether a health practitioner’s breach of duty has caused or contributed to a patient’s injury, the court would consider⁸⁰³ (a) the ‘legal causation’, i.e. the interrelationship between the scope of duty and causation by considering its remoteness and foreseeability, (b) the ‘factual causation’ by applying rules such as the ‘but for’ test,⁸⁰⁴ material increase of risk and material contribution, as well as (c) the limits on the scope of duty. To establish remoteness, a claimant has to prove that the injury was not only caused by the health practitioner’s breach of duty but also that the injury was foreseeable.⁸⁰⁵ Such proof is required no matter whether or not there was a contract.⁸⁰⁶

5.6.1.2 The ‘But For’ Test

A court will compare what has actually happened and what would have happened if the alleged negligent acts or omissions had not occurred.⁸⁰⁷ On the balance of probabilities, if the medical adverse outcome would not have happened but for the practitioner’s breach, the breach is a cause. If such outcome would have occurred anyway irrespective of the negligence, it is not a cause.⁸⁰⁸ While the ‘but for’ test is most commonly used in clinical negligence cases, this test is not the only test of factual causation⁸⁰⁹ and is not a panacea to all medical negligence cases, either. It ‘merely acts as preliminary filter and eliminates the irrelevant.’⁸¹⁰ In *Smith New Court Securities Ltd v Scrimgeour Vickers (Asset Management) Ltd* in the UK, Lord Steyn in the House of Lords said, “... the ‘but for’ test, although it often yields the

⁸⁰⁰ Emily Jackson (n 325) 140-141.

⁸⁰¹ United Kingdom, Chief Medical Officer (n 230) 110 [5].

⁸⁰² Woolf (1996) (n 308) Chapter 15 [5].

⁸⁰³ Powell, Stewart and Jackson (eds) (2007) (n 391) 988 [13-107].

⁸⁰⁴ *Barnett v Chelsea & Kensington Hospital Management Committee* [1969] 1 QB 428, [1968] 1 All ER 1068 (High Court Queen’s Bench).

⁸⁰⁵ Powell, Stewart and Jackson (eds) (2007) (n 391) 1023 [13-149].

⁸⁰⁶ Dunn (ed) (2010) (n 415) 25.

⁸⁰⁷ *Ibid* 19.

⁸⁰⁸ *Ibid*.

⁸⁰⁹ *Ibid*.

⁸¹⁰ Percy Henry Winfield, *Winfield and Jolowicz on tort* (18th edn, Sweet & Maxwell, London 2010) 311 [6-6].

right answer, does not always do so.”⁸¹¹ The High Court of Australia in *Chappel v Hart*⁸¹² also held similarly that although the ‘but for’ test would often be relevant and useful to help resolve the issue of causation, it was not the exclusive test nor could it establish the necessary causal connection for legal purposes.

5.6.1.3 A ‘Robust and Pragmatic’ Approach to Causation

In a medical claim, it is difficult to determine factual causation when there are several concurrent or successive factors leading to the claimant’s injury or when the real cause is indeterminate. When a claimant is short of evidence and finds it difficult to establish a causal link between his or her injury and the defendant’s breach of the duty of care, a rigid application of the ‘but for’ test might cause injustice to the claimant.⁸¹³ In this sense, the court may apply other tests such as inference or common sense to see if causation between injury and breach of duty could be established. In Canada, no experts from the either side in *Snell v Farrell*⁸¹⁴ could say whether the claimant’s blindness was triggered by the defendant’s negligence or whether the claimant would have suffered from blindness anyway. Sopinka J sitting on the Supreme Court of Canada said,

It is not strictly accurate to speak of the burden shifting to the defendant when what is meant is that evidence adduced by the plaintiff may result in an inference being drawn adverse to the defendant. Whether an inference is or is not drawn is a matter of weighing evidence. The defendant runs the risk of an adverse inference in the absence of evidence to the contrary. This is sometimes referred to as imposing on the defendant a provisional or tactical burden.⁸¹⁵

In the UK, the claimant in *McGhee v National Coal Board*, owing to lack of medical knowledge, could not establish a strict causation between the alleged negligence and

⁸¹¹ [1997] AC 254, 285, [1996] 4 All ER 769 (House of Lords).

⁸¹² [1998] HCA 55, (1998) 195 CLR 232, 72 ALJR 1344, 156 ALR 517 (High Court of Australia).

⁸¹³ Michael G Thomas, ‘Causation in Medical Negligence Cases: A Perspective from British Columbia’ (Continuing Legal Education Society of British Columbia, Canada 2011) 6.1.4.

⁸¹⁴ (1990), 4 CCLT (2d) 229, 110 NR 200, [1990] 2 SCR 311, 72 DLR (4th) 289, 107 NBR (2d) 94, 267 APR 94, (sub nom *Farrel c Snell*) [1990] RRA 660, JE 90-1175, EYB 1990-67315 (Supreme Court of Canada).

⁸¹⁵ Ibid [33] (Sopinka J).

his injury. The House of Lords agreed that common sense could be used to decide whether there was a causal connection between the injury and the defendant's act or omission.⁸¹⁶ In the subsequent *Fairchild v Glenhaven Funeral Services Ltd*,⁸¹⁷ the House of Lords applied *McGhee* and found that in the current medical knowledge, the onset of the claimants' contracting mesothelioma, a cancer due to exposure to asbestos, could not be attributed to any particular or cumulative wrongful exposure. The Court held that the proof that each defendant's wrongdoing had materially increased the risk of the claimants contracting this disease had been sufficient to meet the causal requirements to establish the defendants' liability. In this case, the House of Lords pointed out that the circumstances of *Fairchild* were exceptional and distinguished it from *Wilsher v Essex Area Health Authority*.⁸¹⁸ In *Wilsher*, the Court of Appeal followed *McGhee* and gave judgment for the infant claimant who had received excess oxygen after his premature birth and developed retrolental fibroplasias, an eye disease. Upon appeal, the House of Lords overruled the Court of Appeal's decision and distinguished the case from *McGhee* in that whilst there was only one possible agent causing the claimant's skin disease in *McGhee*, there were a number of possible agents which could have caused the claimant's eye disease in *Wilsher*. Excessive supply of oxygen was one of the possible agents but no one could conclude if excess oxygen had or had not caused or contributed to the claimant's injury.⁸¹⁹ The House of Lords considered that the burden of proof was reversed and held that the claimant need not only prove that the excessive supply of oxygen increased the risk of the eye disease but actually caused or contributed to it. Waller LJ sitting on the Court of Appeal said in *Bailey v Ministry of Defence*, "In a case where medical science cannot establish the probability that 'but for' an act of negligence the injury would not have happened but can establish that the contribution of the negligent cause was more than negligent, the 'but for' test is modified, and the Claimant will succeed."⁸²⁰ Dunn has suggested that *McGhee* and *Fairchild* will have little impact to clinical negligence cases and it seems likely that the English courts will continue to apply *Wilsher* to causation in medical claims.⁸²¹ Thomas, after

⁸¹⁶ [1973] 1 WLR 1, [1972] 3 All ER 1008 (House of Lords).

⁸¹⁷ [2002] UKHL 22, [2003] 1 AC 32.

⁸¹⁸ [1988] AC 1074, [1988] 1 All ER 871 (House of Lords).

⁸¹⁹ See Powell, Stewart and Jackson (eds) (2007) (n 391) 996 [13-118] for Browne-Wilkinson's dissenting judgment in the Court of Appeal, which was subsequently approved by the House of Lords.

⁸²⁰ [2008] EWCA Civ 883, [2009] 1 WLR 1052, [46] (Court of Appeal).

⁸²¹ Dunn (ed) (2010) (n 415) 21.

review of medical negligence jurisprudence in the UK and Canada, has also concluded that the courts will likely continue to be reluctant to place liability on health practitioners and institutes when a claimant cannot prove causation on the balance of probabilities.⁸²²

5.6.1.4 Loss of Chance

There has been a question as to whether the law should allow recovery for the loss of chance in the prospect of a better medical outcome in clinical negligence cases; if affirmative, it would mean replacing the normal requirement for probable causation to the lesser standard of possible causation.⁸²³ In the UK, the House of Lords in *Hotson v East Berkshire Area Health Authority*⁸²⁴ did not settle this question, but this is now clear following *Gregg v Scott*,⁸²⁵ where the House of Lords ruled that liability for the loss of a chance of a more favourable outcome should not be introduced into personal injury claims. In Australia, the claimant in *Tabet v Gett*⁸²⁶ alleged the one-day delay of diagnosis of her brain tumour by computerized tomography scan, together with the resultant treatment, had made her lose the chance of better medical outcome. The High Court applied the approach of *Gregg* and held by majority that in a negligence claim arising from personal injury, the loss of a chance of a better medical outcome is not compensable damage. The position of Canada is somewhat interesting. In *Laferrière v Lawson*,⁸²⁷ the Supreme Court of Canada confirmed the approach to loss of chance. While this case was judged in accordance with the civil law of Québec, the Canadian common law courts in Canada consider its judgment authoritative.⁸²⁸ For example, in *Cottrelle v Gerrard*,⁸²⁹ Sharpe JA in the Ontario Court of Appeal said, ‘It is not sufficient to prove that adequate diagnosis and treatment would have afforded a chance of avoiding the unfavourable outcome unless that chance surpasses the threshold of “more likely than not.”’ The

⁸²² Thomas (n 813) 6.1.3.

⁸²³ Powell, Stewart and Jackson (eds) (2007) (n 391) 1003 [13-127].

⁸²⁴ [1987] AC 750, [1987] 2 All ER 909 (House of Lords).

⁸²⁵ [2005] UKHL 2, [2005] 2 AC 176 (House of Lords).

⁸²⁶ [2010] HCA 12 (2010) 240 CLR 537, 84 ALJR 292 (High Court of Australia).

⁸²⁷ (1991), 6 CCLT (2d) 119, 123 NR 325, 38 QAC 161, 78 DLR (4th) 609, [1991] RRA 320, [1991] 1 SCR 541, JE 91-538, EYB 1991-67747 (Supreme Court of Canada).

⁸²⁸ Khoury (n 376) 108.

⁸²⁹ (2003), 178 OAC 142, 233 DLR (4th) 45, 20 CCLT (3d) 1, 67 OR (3d) 737 (Ontario Court of Appeal), [25].

Alberta Court of Queen's Bench in *O'Grady v Stokes*⁸³⁰ also followed *Laferrière* and ruled that it was not sufficient for the claimant to show that her injuries were caused 'possibly' by the defendant's negligence nor was it enough to prove that there was a loss of chance in avoiding the injury.

5.6.1.5 Material Contribution

A health practitioner will be held liable when a claimant can prove that the defendant's breach was a material contribution to the patient's damage⁸³¹ and that if properly informed the patient would not have chosen the treatment causing injury.⁸³² In Australia, the High Court in *Chappel v Hart*⁸³³ held that in clinical negligence cases, a doctor had a duty to warn a patient of 'material risk inherent in a proposed procedure'. In the UK, the House of Lords in *Chester v Afshar* modified the 'but for' test with regard to health practitioners' failure to warn of risks of treatment. Lord Steyn said, '... as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right of autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles.'⁸³⁴

5.6.1.6 Remoteness

In order to succeed in proving factual causation, a claimant has to prove that the damage in an alleged clinical negligence event is not too remote.⁸³⁵ In the UK, the test of remoteness established by the Privy Council (Australia) in *Overseas Tankship (UK) Ltd v Morts Dock & Engineering Co (The Wagon Mound)* requires that the type of damage must be foreseeable. Otherwise, a defendant would not be held liable.⁸³⁶ The Court of Appeal in *R v Croydon Health Authority* dismissed the claim for damages as '[it] was ... too remote. The chain of events had too many

⁸³⁰ 2005 ABQB 247, [2005] AWLD 2340, 50 Alta LR (4th) 98, 375 AR 109, [2006] 6 WWR 144 (Alberta Court of Queen's Bench), [200].

⁸³¹ Powell, Stewart and Jackson (eds) (2007) (n 391) 993 [13-115].

⁸³² Rick Glofcheski, *Tort Law in Hong Kong* (2 edn, Sweet & Maxwell Asia, Hong Kong 2007), 118.

⁸³³ [1998] HCA 55, (1998) 195 CLR 232, 72 ALJR 1344, 156 ALR 517 (High Court of Australia).

⁸³⁴ [2004] UKHL 41, [2005] 1 AC 134, 146 [24] (House of Lords).

⁸³⁵ Emily Jackson (n 325) 147.

⁸³⁶ [1961] AC 388, [1961] 1 All ER 404 (Privy Council (Australia)).

links.’⁸³⁷ The House of Lords in *Page v Smith* held that when damage is foreseeable, it does not concern whether the injury in fact is physical, psychiatric or both.⁸³⁸

5.6.1.7 *Novus Actus Interveniens*

The doctrine of *novus actus interveniens* is a legal tool ‘developed to articulate in practice the extent of any liable defendant’s responsibility for the loss and damage which the claimant has suffered’,⁸³⁹ which holds that an intervener’s intervention may break the causal chain reacted by a person’s negligent act leading to another’s injury and may relieve that person’s responsibility and make him or her not liable for the injury.⁸⁴⁰ In the UK, the question before the House of Lords in *Hogan v Bentinck West Hartley Collieries*⁸⁴¹ was whether the claimant’s incapacity was caused by an original accident or by the intervention of a *novus actus* which broke ‘the chain of causation’. In *Alcock v Chief Constable of South Yorkshire Police*,⁸⁴² a disaster occurred during a football match in which 95 people died and many people were injured. All claimants were friends or relatives of the victims who either saw them on television being broadcast, witnessed the disaster from other parts of the stadium, or heard of it and later saw the victims on television recordings. All suffered shock and psychiatric illness and claimed damages in negligence from the defendant. The House of Lords dismissed the appeal and held that in a claim for psychiatric illness arising from shock, a claimant had to show the reasonable foreseeability of injury and the sufficiently proximate relationship between the claimant and the defendant. The proximation was based on proven ‘ties of love and affection’,⁸⁴³ not based on particular relationships such as spouses. Careful scrutiny was required for remoter relationships and a claimant had to show propinquity in time and space to the accident or its immediate aftermath. The House of Lords found that the claimants’ cases did not show any evidence of particularly close ties of love or affection and the mere fact of the relationship was not sufficient to give rise to a duty of care. Also, with regard to the question about the claimants’ viewing the disaster on television,

⁸³⁷ [1998] PIQR Q26, Q32, [1998] Lloyd’s Rep Med 44 (Court of Appeal) (Kennedy LJ).

⁸³⁸ [1996] AC 155, [1995] 2 All ER 736 (House of Lords).

⁸³⁹ *Rahman v Arearose Ltd* [2001] QB 351, [2000] 3 WLR 1184, (2001) 62 BMLR 84 (Court of Appeal, UK), [33] (Laws LJ).

⁸⁴⁰ Dennis Klimchuk, ‘Causation, Thin Skulls and Equality’ (1998) XI(1) Canadian Journal of Law and Jurisprudence 115, 122.

⁸⁴¹ [1949] 1 All ER 588, [1949] WN 109, [1949] LJR 865 (House of Lords).

⁸⁴² [1992] 1 AC 310 (House of Lords)

⁸⁴³ Ibid 311.

Stock LJ sitting on the House of Lords said, '[T]elevision broadcast of the type which it seems occurred is not to be equated with the plaintiff being within "sight or hearing of the event or its immediate aftermath" and therefore shock sustained by reason of the broadcast would not suffice to found a claim. Such a broadcast, containing substantial elements of editing together with a commentary, is in my view a "novus actus interveniens."'⁸⁴⁴ In *Knightley v Johns*,⁸⁴⁵ the Court of Appeal held that proof of a tortfeasor's negligence which leads to a sequence of natural and probable and therefore foreseeable events is not conclusive on the question of *novus actus interveniens*, but a negligent action was more likely than inaction to be a *novus actus interveniens* to break the chain of causation.

5.6.2 Civil Law in China

The civil law jurisdictions decide causation in a different manner. In China, after assessment of a clinical negligence claim based on its facts and 'irrefutable evidences by making comprehensive analysis of the ... illness of the patient concerned and the differences between ... individuals',⁸⁴⁶ the experts appointed by a society of medical sciences to provide technical authentication (professional assessment) for the claim under the Chinese HMA Regulation 2002⁸⁴⁷ have to produce a letter of authentication of medical accidents, the production of which is subject to a majority rule (over 50%). In the letter of authentication, the experts have to conclude, among others, whether the medical treatment has violated any laws, regulations, ministerial rules concerning medical treatment and health, or any standards or conventions of medical treatment and nursing, and whether there is a causal relationship between 'the negligent medical act and the consequence of personal injury'.⁸⁴⁸

5.6.3 Causation and Telemedicine

Causation is not a topic generally described in the literature in the context of telemedicine. In a telemedicine clinical negligence claim within the same jurisdictions, courts may follow the traditional principles of causation to consider the

⁸⁴⁴ Ibid 380 (Stock LJ).

⁸⁴⁵ [1982] 1 WLR 349, [1982] 1 All ER 851 (Court of Appeal).

⁸⁴⁶ China, Regulation on the Handling of Medical Accidents of People's Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 31.

⁸⁴⁷ Ibid art 20.

⁸⁴⁸ Ibid art 31.

case. However, the issue of causation becomes complicated when the case concerned a telemedical practice across state lines or cross-border, especially when both common law and civil law systems are involved like the cross-border practices between Hong Kong and China. Considerations on the conflict of laws may also arise. Details are to be dealt with in Chapter 8.

5.7 Chapter Conclusion

In this chapter, legal issues concerning health practitioners' standard of care are examined. Others issues about proof of the duty of care and causation are also briefly covered.

Telemedicine being one of the medical technological developments affects health practitioners' standard of care.⁸⁴⁹ In conventional clinical practices, whether a health practitioner has fulfilled his or her duty of care by exercising a reasonable standard of care for a patient is subject to different legal tests in different territorial districts or countries. Such tests are also different in common-law and civil-law jurisdictions. Likewise, telemedicine is also subject to different standards of care around the globe. Telemedicine raises new concerns about the standard of care when health care is delivered in the cyber environment. One of the issues embedded in telemedicine is whether the standard of a patient's home or the one of a remote telehealth practitioner's home should prevail. Another issue relates to regulatory barriers set up by different territories in the form of credentialing and licensing. More than that, telemedicine challenges traditional standards to the extent that patients and courts may set new standards, for instance, by making use of online materials such as health information culled from websites to assess the conduct of health practitioners in clinical negligence cases involving telemedicine.

While health practitioners practise medicine in a new virtual platform, it has not been tested in courts that what standard of care is considered 'acceptable' in the virtual environment and what other new standards are 'applicable' in telemedical applications.⁸⁵⁰ It is not clear how courts may decide an alleged clinical negligence claim in a telemedicine setting,⁸⁵¹ either. The scholarly guesses are that courts may consider legal principles in conventional clinical negligence cases, e.g. medical

⁸⁴⁹ *Hall v Hilbun* 466 So.2d 856 (Miss., 1985) (Supreme Court of Mississippi).

⁸⁵⁰ Fleisher and Datta (n 27) 1-34 §1.04.

⁸⁵¹ Herscha (n 530) 104 [33].

knowledge at the material time of an alleged medical adverse event, status of a defendant health practitioner, and his or her specialty of practice. On top of this conventional approach, courts may also take into account other impact of telemedicine on the standard of care. Using online materials as an example again, health practitioners' easy access to health information on the Internet may have created a 'standard of care minefield'⁸⁵² for them to an extent that the enhanced access to medical reference may affect the standard of care of 'an ordinary competent man exercising that particular art'⁸⁵³ or 'a normal, prudent practitioner of the same experience and standing'.⁸⁵⁴ Health practitioners and/or institutes may also have provided substandard services if telemedical services have not been made available for patients in a timely manner.⁸⁵⁵

⁸⁵² Sokol and Molzen (n 619) 478.

⁸⁵³ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

⁸⁵⁴ *Crits v Sylvester* (1956), [1956] OR 132 (Ontario Court of Appeal).

⁸⁵⁵ Kuszler (n 5) 316.

CHAPTER 6

Other Areas of the SIREN Liability Framework (1): Patients' Concerns

‘This is the real world ... There’s no way to stop [the Web].
If you throw up your hands and get angry,
you’re just going to alienate patients.’

— George D Lundberg⁸⁵⁶

6.1 Chapter Summary

In the previous two chapters, medical liability of health practitioners in telemedicine has been addressed. In Chapters 6 and 7, the remaining elements of the SIREN liability framework, which are generally categorized into three aspects: (a) patients' concerns: patient safety, patient data protection and patient liability, (b) institutional concerns: organizational liability, service liability, product liability and contractual liability, and (c) criminal liability, will be discussed. In this chapter, discussion is made on patients' concerns, leaving institutional issues and criminal liability to the next chapter.

6.2 Liability from the Perspective of Patients

Health practitioners may not know patients' concerns well. Although it is self-evident that patients' needs, values and wishes can be addressed through patient-centred communication, health practitioners and patients may not communicate in such a manner. Marvel and colleagues found that doctors soliciting a full agenda of patients spent only 6 seconds more on average than those interrupting patients to express their concerns,⁸⁵⁷ but patient-centred communication is found to be absent from primary care visits.⁸⁵⁸ This lack of effective communication also leads to an enhanced risk of clinical negligence litigation. In the UK, Vincent and colleagues surveyed 227 claimants in clinical negligence litigation and observed that over 70% of them took legal action not only because of the original injury but also owing to

⁸⁵⁶ Cited in Deborah A Grandinetti, ‘Doctors and the Web: Help your patients surf the Net safely’ (2000) 77(5) *Medical Economics* 186.

⁸⁵⁷ M Kim Marvel, Ronald M Epstein, Kristine Flowers and Howard B Beckman, ‘Soliciting the Patient’s Agenda: Have We Improved?’ (1999) 281(3) *Journal of the American Medical Association* 283, 287.

⁸⁵⁸ Ronald M Epstein, Larry Mauksch, Jennifer Carroll and Carlos Roberto Jaén, ‘Have You Really Addressed Your Patient’s Concerns?’ (2008) 15(3) *Family Practice Management* 35.

insensitive handling and poor communication after the injury – less than 15% considered explanations given to them were satisfactory and 41.4% responded that they would drop their claims if the defendants could have done some action after the original injury incident, where they considered explanation and apology the most important and financial compensation was only ranked the third.⁸⁵⁹ In order to improve communications between health practitioners and patients, it has been suggested that prior to consultation, health practitioners may help patients address their concerns more efficiently and effectively by asking patients to identify their needs at home or in the waiting room first through the use of written or online forms.⁸⁶⁰

6.2.1 Patient Safety

One of the statements of the Hippocratic Oath says, ‘I will prescribe regimens for the good of my patients according to my ability and my judgement and never do harm to anyone.’⁸⁶¹ Whilst new doctors have to swear the Oath to uphold their pledges to never do harm to anyone, medical adverse events occur not rarely. The WHO launched the World Alliance for Patient Safety in 2004 out of international concerns about patient safety.⁸⁶² In Europe, about 8-12% of inpatients suffer from adverse events whilst receiving health services.⁸⁶³ In the UK, medical errors are also the subject of much government attention. The British Department of Health estimated that 850,000 adverse events occurred each year,⁸⁶⁴ and the Chief Medical Officer for England said that up to one-tenth of hospital admissions may lead to medical errors to some degree.⁸⁶⁵ The NHS listed clinical negligence as one of the performance indicators for 2003 for acute and specialist Trusts.⁸⁶⁶ In the US, the

⁸⁵⁹ C Vincent, M Young and A Phillips, ‘Why do people sue doctors? A study of patients and relatives taking legal action.’ (1994) 343(8913) *Lancet* 1609, 1609.

⁸⁶⁰ Epstein and others, ‘Have You Really Addressed Your Patient's Concerns?’ (n 858).

⁸⁶¹ Michael North (tr), *The Hippocratic Oath* (United States National Library of Medicine 2002) <http://www.nlm.nih.gov/hmd/greek/greek_oath.html> accessed 16 March 2011.

⁸⁶² World Health Organization, World Alliance for Patient Safety, *WHO Guidelines for Safe Surgery* (1st edn, WHO Press, Geneva, Switzerland 2008) 7.

⁸⁶³ European Commission, ‘Patient Safety – Policy’

<http://ec.europa.eu/health/patient_safety/policy/index_en.htm> accessed 5 June 2012.

⁸⁶⁴ United Kingdom, Department of Health, *Building a safer NHS for patients: implementing an organization with a memory* (Department of Health, London 2001) 10.

⁸⁶⁵ United Kingdom, Chief Medical Officer (n 230) 8.

⁸⁶⁶ Sheila Leatherman and Kim Sutherland, *The Quest for Quality in the NHS: A mid-term evaluation of the ten-year quality agenda* (The Nuffield Trust, London 2003) 65-66 and Box 6.2.

Institute of Medicine has estimated that 44,000-98,000 people die in hospitals per annum as a result of medical errors and lapses in patient safety.⁸⁶⁷

While institutional stakeholders worry about this trend at the international and national levels, the general public share the same concern, too. In the US, surveys revealed that Americans only perceived the health care they received as moderately safe and about three quarters of them were much concerned about medical errors during hospitalization.⁸⁶⁸ Seeing such a high prevalence of avoidable medical adverse events, Emanuel and colleagues call on organizations to adopt a definition and model for patient safety, which offers four main domains of patient safety: patients, health practitioners, systems of therapeutic action, and methods and elements within each domain.⁸⁶⁹ Patients also contribute to the risks. After patients go home from health practitioners' offices or health institutes, they take care of their own health care. However, there are often compliance and adherence problems to their treatment plans,⁸⁷⁰ possibly owing to their misunderstanding of the treatment plans, lack of access to facilities needed for the plans, and lack of continuous guidance for them to comprehend complex treatments.⁸⁷¹

Telemedicine is a double-edge sword. It helps improve patient safety but at the same time creates a new set of safety risks. On the one hand, tele-monitoring enhances patients' compliance rate by continuous monitoring and communicating with them beyond a healthcare setting.⁸⁷² The use of computerized physician-order entry systems and bar coding can also reduce medication errors, convert medical records from a paper to an electronic format, and facilitate sharing of critical patient information in real time.⁸⁷³ On the other hand, patients' misunderstanding of advice

⁸⁶⁷ The Institute of Medicine of the United States, *To Err Is Human: Building a Safer Health System* (Brief Report) (November 1999) 1 <<http://iom.edu/-/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf>> accessed 10 June 2012.

⁸⁶⁸ Thomas E Burroughs and others, 'Patients' Concerns About Medical Errors During Hospitalization' (2007) 33(1) *Journal on Quality and Patient Safety* 5, 5.

⁸⁶⁹ Linda Emanuel and others, *What Exactly Is Patient Safety?* (Agency for Healthcare Research and Quality, Rockville, Maryland, United States 2008).

⁸⁷⁰ Loretta Schlachta-Fairchild, Victoria Elfrink and Andrea Deickman, 'Patient Safety, Telenursing, and Telehealth' in *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (AHRQ Publication No. 08-0043, Agency for Healthcare Research and Quality, Department of Health and Human Services, Rockville, Maryland, United States, 2008) 2.

⁸⁷¹ Jennifer W Adkins, Eric A Storch, Adam B Lewin, Laura Williams, Janet H Silverstein, Toree Malasanos and Gary R Geffken, 'Home-based behavioral health intervention: Use of a telehealth model to address poor adherence to type-1 diabetes medical regimens.' (2006) 12(3) *Telemedicine Journal and e-health* 370.

⁸⁷² Schlachta-Fairchild, Elfrink and Deickman (n 870) 2-3.

⁸⁷³ Arthur A Levin, 'Patient Safety: Rejecting the Status Quo' (2005) 66(2) *North Carolina Medical Journal* 91, 91.

given through the Internet, technical errors in the use of telemedicine such as malfunctioning of telemedical equipment, poor clinical decisions arising from any delayed or missing patient data in the transmission process, as well as other errors committed by patients or health practitioners become new risk factors.⁸⁷⁴

6.2.1.1 Informed Consent in General

Informed consent is ‘the cornerstone of the contemporary physician-patient relationship’.⁸⁷⁵ It is also one of the factors contributing to patient safety. Health practitioners have legal and ethical obligations to seek all patients’ informed consent to ensure patient safety and the provision of equitable patient-centred services. Informed consent helps enhance patient safety in various aspects. The US Agency for Healthcare Research and Quality has advocated informed consent as one of the top 11 evidence-based patient safety practices.⁸⁷⁶ The WHO also pointed out that routine preoperative procedures could reduce surgical errors through, among others, informed consent to help ensure health practitioners operate on the correct patient at the correct site.⁸⁷⁷ To enhance patient safety in the process of soliciting patient consent, health practitioners need to pay special attention to their communication skills, especially for vulnerable patient groups such as those with language barriers.⁸⁷⁸

Informed consent governs professional and ethical conduct. Professional entities always require their members to explain the risks, benefits and consequences of proposed treatments and obtain patients’ informed consent. The General Medical Council of the UK has set out principles for informed consent and asked doctors to explain the potential benefits, risks, burdens and side effects of the treatment options and of having no treatment to patients.⁸⁷⁹ Other professional organizations in Canada have spelt out the core competencies of various disciplines of health practitioners. For example, one of them asks physiotherapists to inform patients about the nature and

⁸⁷⁴ Schlachta-Fairchild, Elfrink and Deickman (n 870) 6.

⁸⁷⁵ Mark G Kuczewski, ‘Talking about Spirituality in the Clinical Setting: Can Being Professional Require Being Personal?’ (2007) 7(7) *The American Journal of Bioethics* 4, 5.

⁸⁷⁶ United States, Agency for Healthcare Research and Quality, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* (Evidence Report/Technology Assessment No. 43, AHRQ Publication 01-E058, 2001) 6.

⁸⁷⁷ World Health Organization, World Alliance for Patient Safety (n 862) 21.

⁸⁷⁸ Schenker and others (n 180) 298.

⁸⁷⁹ General Medical Council of the United Kingdom, *Consent: patients and doctors making decisions together* (2008) (effective 2 June 2008) (General Medical Council, London 2008) 7 [5].

purpose of assessment and the inherent risks and get patients' consent.⁸⁸⁰

To obtain patients' informed consent is also a legal duty of health practitioners. The law of informed consent requires practitioners to disclose sufficient information for patients to make informed decisions on treatment options, do-not-resuscitate orders, and termination of treatment, etc.⁸⁸¹ In the US, Cardozo J in the Court of Appeals of New York in *Schloendorff v Society of New York Hospital* laid a foundation stone for the doctrine of informed consent in 1914 as follows:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages. This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained.⁸⁸²

In the UK, Neill LJ in the House of Lords in *F v West Berkshire Health Authority*⁸⁸³ said, '[E]verybody is protected not only against physical injury but against any form of physical molestation'⁸⁸⁴ and 'the right to refuse [any operation or treatment] exists even where there are overwhelming medical reasons in favour of the treatment and probably even where if the treatment is not carried out the patient's life will be at risk.'⁸⁸⁵ It has been generally recognized by the courts that doctors have a fiduciary duty to disclose the purpose of informed consent.⁸⁸⁶ The House of Lords in *Sidaway v Governors of Bethlem Royal Hospital*⁸⁸⁷ by a majority held that the *Bolam*⁸⁸⁸ test was applicable to all aspects of a health practitioner's work and in particular to his or her

⁸⁸⁰ Accreditation Council for Canadian Physiotherapy Academic Programs, Canadian Alliance of Physiotherapy Regulators, Canadian Physiotherapy Association and Canadian Council of Physiotherapy University Programs, *Essential Competency Profile for Physiotherapists in Canada* (2009) 6 [1.2.2] and [1.2.3].

⁸⁸¹ William M Altman, Patricia A Parmelee and Michael A Smyer, 'Autonomy, Competence, and Informed Consent in Long-Term Care: Legal and Psychological Perspectives' in Lawrence A Frolik (ed), *Aging and the Law* (Temple University Press, Philadelphia, United States, 1999) 298.

⁸⁸² *Schloendorff v Society of New York Hospital* 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (N.Y. 1914) (Court of Appeals of New York). This case is no longer good for at least one point of law.

⁸⁸³ [1990] 2 AC 1, [1989] 2 All ER 545 (House of Lords).

⁸⁸⁴ *Ibid* 27.

⁸⁸⁵ *Ibid* 29.

⁸⁸⁶ Richard A Heinemann, 'Pushing the Limits of Informed Consent: *Johnson v. Kokemoor* and Physician-Specific Disclosure' (1997) 1997(5) Wisconsin Law Review 1079, 1090 Footnote 66.

⁸⁸⁷ [1985] AC 871, [1985] 1 All ER 643 (House of Lords).

⁸⁸⁸ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

duty to inform a patient of the risks of a proposed course of treatment.⁸⁸⁹ In *Bolitho v City and Hackney HA*, the House of Lords endorsed *Sidaway* and held that when an alleged negligence is connected with a failure to disclose sufficient information prior to obtaining a patient's consent, a court can reach its own view as to what constitutes responsible medical practice.⁸⁹⁰ The requirements for health practitioners to obtain patients' informed consent have also been legislated into law. In the UK, the Private and Voluntary Health Care (England) Regulations 2001 requires a hospital to assess the competence of each patient to give consent to treatment⁸⁹¹ and to ensure that patients' consent is obtained before any research is carried out.⁸⁹² In the US, the Code of Federal Regulations has promulgated a set of requirements for informed consent, including an explanation of the purposes and duration of a research, any foreseeable risks or any benefits to the subject, a disclosure of any alternative procedures of medical treatment that might be advantageous to the subject, confidentiality of records, any compensation available if injury due to medical treatments occurs, and voluntary participation, etc.⁸⁹³

6.2.1.1.1 Components Constituting Informed Consent

A few components have to exist before consent is considered valid. Consent to scientific experimentation on human subjects contains four attributes as stated in the Nuremberg Code 1947:⁸⁹⁴ 'voluntary', 'legally competent', 'informed' and 'comprehending'.⁸⁹⁵ Correspondingly, there are three components constituting informed consent to health care, namely patients' being free from undue influence or duress, patients' decision-making capacity, and sufficient information provided by health practitioners.⁸⁹⁶ In the context of voluntariness, there should be no coercion, fraud or duress in order to enable competent patients to make healthcare decisions

⁸⁸⁹ [1985] AC 871, [1985] 1 All ER 643 (House of Lords) (agreed by Lord Diplock, Lord Bridge and Lord Keith. Lord Templeman and Lord Scarman agreed with the decision of the majority but on different grounds).

⁸⁹⁰ [1998] AC 232, 234-235, [1997] 4 All ER 771 (House of Lords).

⁸⁹¹ Section 9(3)(a).

⁸⁹² Section 9(1)(j).

⁸⁹³ United States, Code of Federal Regulations (2009) §46.116.

⁸⁹⁴ The Nuremberg Code 1947, Rule 1.

⁸⁹⁵ Robert J Levine, 'Informed Consent: Some Challenges to the Universal Validity of the Western Model' in Z Bankowski, J H Bryant and J M Last (eds), *Ethics and Epidemiology: International Guidelines* (Proceedings of the XXVth CIOMS Conference, Geneva, Switzerland, 7-9 November 1990) (Council for International Organizations of Medical Sciences, Geneva 1991) 47.

⁸⁹⁶ Altman, Parmelee and Smyer (n 881) 298-301.

voluntarily.⁸⁹⁷ It is rare that direct threats are used to force patients to give consent to treatment, but more subtle forms are possible.⁸⁹⁸ In *Re T (Adult: Refusal of Treatment)* in the UK, the court recognized that the usual pressure for patients to give consent or refusal to healthcare treatment comes from persuasion, rather than physical threat or duress. Donaldson of Lymington MR said, ‘The real question in each such case is “Does the patient really mean what he says or is he merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself?”’⁸⁹⁹

As for patients’ decision-making capacity, Thorpe J in *Re C (Adult: Refusal of Medical Treatment)*⁹⁰⁰ in the UK proposed a three-stage test to establish whether a patient has capacity to give consent: whether the patient comprehends the relevant information, whether he or she is able to believe it, and whether he is able to weigh the information, balance the risks and benefits and reach a decision. The discourse on patients’ capacity has been extended to adolescents. The House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority*⁹⁰¹ established that the parental right to determine if a child under 16 years old should have medical treatment ends when the child has sufficient intelligence and understanding to consent to medical examination and treatment. In Australia, the High Court in *Secretary, Department of Health and Community Services v J W B and S M B* endorsed the English ruling in *Gillick*.⁹⁰²

A health practitioner who fails to provide sufficient information or have a patient’s consent before treatment may be liable for assault and battery as well as negligence. A battery has been prima facie committed if he or she physically touches a patient without consent. In the US, the Supreme Court of Illinois in *Pratt v Davis*⁹⁰³ affirmed the lower courts’ judgment for the claimant in an action for trespass to the person against the defendant’s undergoing an operation without consent. In *Scott v Bradford*,⁹⁰⁴ the Supreme Court of Oklahoma pointed out that a health practitioner commits a battery if the treatment is completely unauthorized and performed without

⁸⁹⁷ Altman, Parmelee and Smyer (n 881) 301.

⁸⁹⁸ Emily Jackson (n 325) 248.

⁸⁹⁹ [1992] 3 WLR 782, [1993] Fam 95, 113 (Court of Appeal).

⁹⁰⁰ [1994] 1 WLR 290, 292, [1994] 1 All ER 819 (High Court Family Division).

⁹⁰¹ [1986] AC 112 (House of Lords).

⁹⁰² [1992] HCA 15, (1992) 175 CLR 218, 66 ALJR 300, 106 ALR 385 (High Court of Australia).

⁹⁰³ 224 Ill. 300, 79 N.E. 562 (Ill. 1906) (Supreme Court of Illinois).

⁹⁰⁴ 606 P.2d 554, 557, 1979 OK 165 (Ok., 1980) (Supreme Court of Oklahoma).

patient consent. In *Moure v Raeuchele*, McDermott J in the Supreme Court of Pennsylvania said, '[S]ince the tort founded upon lack of informed consent is an intentional tort, i.e. a battery, the issue of negligence is not germane.'⁹⁰⁵ In fact, health practitioners may also be found negligent and liable for their failure to disclose sufficiently. If the health practitioner discloses information to a patient in a way not meeting the duty of care and the patient is injured, the patient has a cause of action in negligence for the practitioner's failure to disclose information, regardless of due care being exercised in treatment. In *Salgo v Leland Stanford Jr. University Bd. of Trustees*, Bray J in the District Court of Appeal of California in the US said, 'A physician violates his duty to his patient ... if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.'⁹⁰⁶ In Australia, King CJ sitting on the Supreme Court of South Australia in *F v R*⁹⁰⁷ said, 'Some cases, particularly in the United States of America where the doctrine of "informed consent" is highly developed in a number of jurisdictions, are concerned with the amount of information which must be conveyed to the patient before his consent to treatment can be regarded as real consent.' *F v R* departed from the English test of *Bolam*⁹⁰⁸ with regard to the duty of health practitioners to disclose risks to a patient and held that while in many cases the issue of negligence was decided based on whether a defendant's conduct conformed to approved professional practice, the ultimate question is for the court, not any professional bodies, to decide whether a defendant's conduct has conformed to the standard of reasonable care demanded by the law.⁹⁰⁹ Despite years of development, the issue on sufficient information is still a controversial topic.⁹¹⁰ In *Kong Wai Tsang v Hospital Authority*, Bokhary PJ in the Court of Final Appeal of Hong Kong said, 'The availability of negligent failure to warn as a basis of claim is widely recognized ... Even so, it represents what is very much a developing area of the law.'⁹¹¹

⁹⁰⁵ 529 Pa. 394, 404 Footnote 8, 604 A.2d 1003, 1008 Footnote 8 (Pa., 1992) (Supreme Court of Pennsylvania)

⁹⁰⁶ 154 Cal.App.2d 560, 578, 317 P.2d 170, 181 (Cal.App.1.Dist. 1957) (District Court of Appeal of California, First District).

⁹⁰⁷ (1983) 33 SASR 189, 191, 1984 WL 282259 (Supreme Court of South Australia).

⁹⁰⁸ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

⁹⁰⁹ (1983) 33 SASR 189, 194, 1984 WL 282259 (Supreme Court of South Australia).

⁹¹⁰ *Glofcheski* (n 832) 54.

⁹¹¹ [2006] HKEC 528, [5] (Court of Final Appeal).

6.2.1.1.2 Standards of ‘Informed’ Consent

Case law has developed three legal standards to assess consent to see if it is ‘informed’ consent: (a) a provider-centred approach as to what reasonable health practitioners would disclose in similar circumstances, (b) a patient-centred approach requiring practitioners to disclose information that reasonable patients in similar circumstances would want to know before making informed decisions, and (c) a purely subjective approach that demands health practitioners to disclose information that a particular individual patient would want to know.⁹¹² Different jurisdictions have adopted different approaches. In *F v R* in Australia, King CJ sitting on the Supreme Court of South Australia gave a concise summary about this and said,

Determination of the scope of the doctor’s duty to disclose involves consideration of two values which are sometimes in conflict, namely the duty of the doctor to act in what he conceives to be the best interests of his patient and the right of the patient to control his own life and to have the information necessary to do so. The decided cases in England have tended to place the emphasis on the former value and in consequence to formulate the test of negligence largely, and sometimes exclusively, in terms of the extent of disclosure required by the practice prevailing in the medical profession ... In the United States, and to some extent in Canada, there is a tendency to place greater weight on the patient’s right to receive the information which is necessary for an informed decision as to whether to undergo the proffered treatment, that is to say on what is often termed in the United States “the right of self determination” ...⁹¹³

King CJ’s citation in 1984 above pointed out the issue about the use of different standards of informed consent in different common law jurisdictions. The English legal system traditionally applies a provider-based standard in relation to disclosure of risk,⁹¹⁴ and the US, Australia and Canada approach this issue differently.⁹¹⁵ In the US, *Canterbury v Spence* is one of the cases advocating the patient-based standard of

⁹¹² Altman, Parmelee and Smyer (n 881) 300.

⁹¹³ (1983) 33 SASR 189, 191, 1984 WL 282259 (Supreme Court of South Australia).

⁹¹⁴ Majid Hassan, ‘Informed Consent and the Law – An English Legal Perspective’ (2008) 26(1) Digestive Diseases 23.

⁹¹⁵ Glofcheski (n 832) 530.

disclosure, where the US Court of Appeals for the District of Columbia Circuit held that ‘[r]espect for the patient’s right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.’⁹¹⁶ In Australia and Canada, health practitioners have to take into account the nature of a patient’s illness, explain to the patient the inherent risks of the proposed treatment, and consider alternative treatments including the resultant risks.⁹¹⁷ The Australian and Canadian courts also consider what a reasonable patient would like to know, rather than what a health practitioner wants the patient to know. In *Rogers v Whitaker*,⁹¹⁸ the High Court of Australia did not follow *Sidaway v Governors of Bethlem Royal Hospital*⁹¹⁹ in the UK and ruled that ‘In Australia, ... in the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded ... [I]t is for the courts to adjudicate on what is the appropriate standard of care after giving weight to “the paramount consideration that a person is entitled to make his own decisions about his life”’.⁹²⁰ In *Arndt v Smith*,⁹²¹ the Supreme Court of Canada considered Laskin CJC’s ‘modified objective test for causation’ in *Reibl v Hughes*⁹²² significant and leading, as it ‘marks the rejection of the paternalistic approach to determining how much information should be given to patients [and] emphasizes the patient’s right to know and ensures that patients will have the benefit of a high standard of disclosure.’⁹²³ Under the third legal standard, i.e. a subjective patient standard, needs of a particular patient, instead of reasonable patients, would be measured. In the US, the Supreme Court of Oklahoma in *Scott v Bradford* adopted this approach by a majority, where Doolin J said,⁹²⁴

To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar

⁹¹⁶ 464 F.2d 772, 784, 150 U.S.App.D.C. 263, 275 (C.A.D.C., 1972) (United State Court of Appeals for the District of Columbia Circuit).

⁹¹⁷ Powell, Stewart and Jackson (eds) (2007) (n 391) 917 Footnote 17.

⁹¹⁸ [1992] HCA 58, (1992) 175 CLR 479, 67 ALJR 47, 109 ALR 625, [1993] 4 Medical Law Reports 79 (High Court of Australia).

⁹¹⁹ [1985] AC 871, [1985] 1 All ER 643 (House of Lords).

⁹²⁰ *Rogers v Whitaker* [1992] HCA 58, (1992) 175 CLR 479, 487.

⁹²¹ (1997), 213 NR 243, 92 BCAC 185, 150 WAC 185, 148 DLR (4th) 48, 35 CCLT (2d) 233, [1997] 2 SCR 539, 35 BCLR (3d) 187, [1997] 8 WWR 303 (Supreme Court of Canada).

⁹²² (1980), 14 CCLT 1, 114 DLR (3d) 1, 33 NR 361, [1980] 2 SCR 880, JE 80-894 (Supreme Court of Canada), [23]-[27].

⁹²³ *Arndt v Smith* (1997) 213 NR 243, [15] (Supreme Court of Canada) (Cory J).

⁹²⁴ Lavender CJ, Hodges, Hargrave and Opala JJ concurred, with dissenting opinion from Barnes J.

circumstances would have consented, a patient's right of self-determination is irrevocably lost. This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of the 'reasonable man' standard.⁹²⁵

6.2.1.1.3 Exceptions to the Doctrine of Informed Consent

Patients may withdraw their consent at any time during a procedure.⁹²⁶ Also, there are exceptions to the doctrine of informed consent in the cases of, for instance, emergency,⁹²⁷ therapeutic privilege⁹²⁸ and incapacity of the patient.⁹²⁹ In emergency situations, the Penal Code in Singapore declares that it is not an offence to cause any harm to a person, even without consent, for whose benefit it is done in good faith in circumstances where it is not allowable to obtain that person's consent, or the person has no capacity to give consent, or he or she has no legal guardian from whom a consent can be obtained in time for the thing to be done with benefit.⁹³⁰ Therapeutic privilege is applicable to cases where disclosure of risks of treatment poses 'a threat detrimental to a patient as to become unfeasible or contraindicated from a medical point of view.'⁹³¹ In these cases, health practitioners are justified in withholding information, in particular to refrain from volunteering information or imparting information.⁹³² As for the incapacity of a patient, when a patient is mentally ill or disabled, health practitioners should pay special attention. In the UK, the House of Lords in *F v West Berkshire Health Authority*⁹³³ agreed that doctors could treat incompetent adult patients in their best interests and suggested making use of the *Bolam*⁹³⁴ principles to determine if treatment is in the best interest of a particular patient. In *In Re T (Adult: Refusal of Treatment)*,⁹³⁵ the Court of Appeal dispelled the misconception that the next of kin has a legal right either to consent or to refuse

⁹²⁵ 606 P.2d 554, 559, 1979 OK 165 (Okl., 1980) (Supreme Court of Oklahoma).

⁹²⁶ Powell, Stewart and Jackson (eds) (2007) (n 391) 937 [13-044].

⁹²⁷ Suzanne K Ketler, 'The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine after *Schreiber v. Physicians Insurance Co. of Wisconsin*' (2000-2001) 95(3) Northwest University Law Review 1029, 1035.

⁹²⁸ Sheldon F Kurtz, 'The Law of Informed Consent: From "Doctor Is Right" to "Patient Has Rights"' (2000) 50(4) Syracuse Law Review 1243, 1250.

⁹²⁹ Emily Jackson (n 325) 191-248.

⁹³⁰ Singapore, Penal Code (Chapter 224) section 92.

⁹³¹ *Canterbury v Spence* 464 F.2d 772, 789, 150 U.S.App.D.C. 263, 280 (C.A.D.C., 1972) (United State Court of Appeals for the District of Columbia Circuit) (Robinson CJ).

⁹³² *F v R* (1983) 33 SASR 189, 193, 1984 WL 282259 (Supreme Court of South Australia).

⁹³³ [1990] 2 AC 1, [1989] 2 All ER 545 (House of Lords).

⁹³⁴ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

⁹³⁵ [1992] 3 WLR 782, [1993] Fam 95 (Court of Appeal).

consent on behalf of a patient. The Chinese law treats this issue in a different manner. In China, the Basic Rules of Making Medical Records allow a few exceptions to the doctrine of patients' informed consent. A health practitioner can ask a patients' legal representative to give consent on his or her behalf if the patient is in an incapable condition. If the patient is too weak, the health practitioner can obtain consent from an authorized person. When it is not in the patient's best interests to inform a patient of his or her health conditions, a health practitioner should inform the patient's close relative(s) instead and ask for the consent of the relative(s).⁹³⁶

6.2.1.2 Informed Consent in Telemedicine

6.2.1.2.1 Statutory Requirements

In the context of telemedicine, some jurisdictions have statutory requirements for patients' informed consent. In the US, the Telehealth Advancement Act 2011 in California requires a health practitioner to obtain a patient's verbal consent before he or she carries out any telehealth services and such consent has to be documented in the patient's medical record, failing which the practitioner commits unprofessional conduct.⁹³⁷ The Oklahoma Telemedicine Act 1997 stipulates that a health practitioner has to obtain a patient's written informed consent prior to the delivery of health care via telemedicine and the practitioner has to ensure that the informed consent procedure includes, inter alia, confidentiality protections, the potential risks, consequences and benefits of telemedicine, and a statement that the patient retains the option to withhold or withdraw consent at any time. If the practitioner fails to comply with the statutory provisions, he or she may have committed unprofessional conduct.⁹³⁸ In Malaysia, the Telemedicine Act 1997 also contains requirements comparable to those of the Oklahoma Telemedicine Act 1997 and asks doctors who practise telemedicine to obtain their patients' prior written consent⁹³⁹ and well inform patients that they are free to withdraw the consent at any

⁹³⁶ China, Basic Rules of Making Medical Records (Health and Medical Policy (2010) No. 11) (‘病歷書寫基本規範’，衛醫政發 (2010) 11 號; ‘bìng lì shū xiě jī běn guī fàn’，wèi yī zhèng fà (2010) 11 hào), section 10.

⁹³⁷ United States, California Business and Professions Code §§2290.5(b) & (c).

⁹³⁸ §36-6804.

⁹³⁹ Section 5(1).

time without affecting their right to future care or treatment.⁹⁴⁰

6.2.1.2.2 Electronic Signatures and Communications

In the traditional approach, patients are asked to sign a consent form in paper format. A hard copy of a signed consent form may help prove that informed consent has been obtained for any subsequent legal claims,⁹⁴¹ although case law has pointed out that a signed consent form does not necessarily signify that a patient who gave the consent has understood the nature of the proposed procedures. In *Chatterton v Gerson* in the UK, Bristow J said, “[G]etting the patient to sign a pro forma expressing consent to undergo the operation ... would be no defence to an action based on trespass if no explanation had in fact been given. The consent would have been expressed in form only, not in reality.”⁹⁴²

Contrary to the traditional approach, telemedicine patients may sign their informed consent over the Internet. The UN defines electronic signature as ‘data in electronic form in, affixed to or logically associated with, a data message, which may be used to identify the signatory in relation to the data message and to indicate the signatory’s approval of the information contained in the data message’.⁹⁴³ How to obtain a signature on informed consent from patients online may create a legal problem for telemedicine. In practice, cyber researches may provide a reference for telemedical practices. Online researches face similar issues on how to obtain digital signatures in the virtual environment. In these researches, the informed consent process serves three objectives: (a) To give information on the procedures, the purposes, risks and anticipated benefits, and offering chances for participants to ask questions and withdraw from the surveys, (b) to make sure that participants comprehend the information and what they are consenting to, and (c) to ensure that participants’ consents are given voluntarily.⁹⁴⁴ These objectives are analogous to the purposes of informed consent in clinical practices, which are to protect patients from

⁹⁴⁰ Section 5(2)(a).

⁹⁴¹ Mark D Johns, G Jon Hall and Tara Lynn Crowell, ‘Surviving the IRB Review: Institutional Guidelines and Research Strategies’ in Mark D Johns, Shing-Ling Sarina Chen and G Jon Hall (eds), *Online Social Research: Methods, Issues, & Ethics* (Peter Lang Publishing, New York 2004) 115.

⁹⁴² [1981] QB 432, 443, [1981] 1 All ER 257 (High Court Queen’s Bench).

⁹⁴³ United Nations, UNCITRAL Model Law on Electronic Signatures, art 2(a).

⁹⁴⁴ Susan B Barnes, ‘Issues of Attribution and Identification in Online Social Research’ in Johns, Chen and Hall (eds) (n 941) 217.

potential harm and provide respect for their personal autonomy.⁹⁴⁵ Liamputtong discussed a few approaches to collecting cyber informed consent in online research, mainly asking participants to check a 'YES' or 'NO' box on the online consent form and when problems arise, asking participants to fax or mail their actually signed consent forms to the researchers.⁹⁴⁶ Despite these measures, there are still concerns about electronic signatures in researches through the Internet, including but not limited to what constitutes a legitimate online signature, the common existence of various forms of electronic signatures on the Internet, no clear standards, and different technologies offering different varying security levels, etc.⁹⁴⁷

The concerns about electronic signatures in cyber researches are applicable to telemedicine. A health practitioner may assume legal responsibility for a clinical document through an electronic signature, e.g. issuance of a medical report. Patients may also give their consent by signing online. What is the legal status of such electronic signatures? This was a difficult question for lawyers who had to ensure the fulfillment of legal requirements that some documents had to be signed.⁹⁴⁸ The EU Directive on Electronic Signatures⁹⁴⁹ issued in 1999 confirms the admissibility of electronic signatures to courts as evidence and they may not be dismissed just because they are in electronic form.⁹⁵⁰ More weight will be attached to the advanced electronic signature, which is uniquely linked to a signatory, created under the sole control of the signatory, and is able to identify the signatory and detect any tampering.⁹⁵¹ The UN also published the UNCITRAL Model Law on Electronic Commerce in 1996. Its article 7 provides that where the law requires a signature of a person, that requirement is met if a method is used to identify that person and to indicate his or her approval of the information contained in a data message⁹⁵² and the method used is reliable for the purpose for which the data message was generated or

⁹⁴⁵ Ruth Macklin, 'Some Problems in Gaining Informed Consent From Psychiatric Patients' (1982) 31(2) Emory Law Review 345, 371.

⁹⁴⁶ Pranee Liamputtong, 'Cyber Research: Focusing on Methodology' in Pranee Liamputtong (ed), *Health Research in Cyberspace* (Nova Science Publishers, New York 2006) 30-31.

⁹⁴⁷ Johns, Hall and Crowell (n 941) 114.

⁹⁴⁸ Jay Forder, 'The inadequate legislative response to e-signatures' (2010) 26(4) Computer Law & Security Review 418, 418.

⁹⁴⁹ European Union, Council Directive 1999/93/EC of 13 December 1999 on a Community framework for electronic signatures.

⁹⁵⁰ Art 5(2).

⁹⁵¹ Art 2(2).

⁹⁵² Art 7(1)(a).

communicated.⁹⁵³ In 2001 the UN issued the UNCITRAL Model Law on Electronic Signatures to establish criteria of technical reliability for the equivalence between electronic and manual signatures. Based on the fundamental principle embedded in article 7 of the 1996 Model Law, the 2001 Model Law establishes a principle of equal treatment for electronic signatures,⁹⁵⁴ and considers an electronic signature reliable if its creation is linked to⁹⁵⁵ and under control of the signatory⁹⁵⁶ and if any alteration to the electronic signature made after its creation is detectable.⁹⁵⁷ In 2005 the UN built upon the 1996 and 2001 Model Laws and further promulgated the Convention on the Use of Electronic Communications in International Contracts.⁹⁵⁸ The 2005 Convention recognizes the legal validity of electronic communications.⁹⁵⁹ It sets out that if there is a legal requirement for a communication or a contract to be in written form or for providing consequences for the absence of writing, that requirement is satisfied by an electronic communication if the information contained therein is accessible so as to be usable for subsequent reference.⁹⁶⁰ It also defines the time and place of dispatch and receipt of electronic communications.⁹⁶¹ According to the UNCITRAL website,⁹⁶² as at the time of writing this thesis, over 40 jurisdictions including Australia,⁹⁶³ New Zealand,⁹⁶⁴ Singapore,⁹⁶⁵ the UK,⁹⁶⁶ Hong Kong⁹⁶⁷ and China⁹⁶⁸ have enacted their national/domestic electronic signature legislation based on the 1996 Model Law. In the US, not every state follows the 1996 Model Law. Treatment of electronic signatures differs from state to state.⁹⁶⁹ Some states follow the guidelines published by industry groups such as the Joint Commission on

⁹⁵³ Art 7(1)(b).

⁹⁵⁴ Art 3.

⁹⁵⁵ Art 6(3)(a).

⁹⁵⁶ Art 6(3)(b).

⁹⁵⁷ Art 6(3)(d).

⁹⁵⁸ United Nation,

⁹⁵⁹ Art 8

⁹⁶⁰ Art 9(2).

⁹⁶¹ Art 10.

⁹⁶² United Nation, United Nation Commission on International Law, 'Status: 1996 – UNCITRAL Model Law on Electronic Commerce'

<http://www.uncitral.org/uncitral/en/uncitral_texts/electronic_commerce/1996Model_status.html> accessed 7 June 2012.

⁹⁶³ Australia, Electronic Transactions Act 1999.

⁹⁶⁴ New Zealand, Electronic Transactions Act 2002.

⁹⁶⁵ Singapore, Electronic Transactions Act 2010 (Chapter 88).

⁹⁶⁶ United Kingdom, Electronic Communications Act 2000.

⁹⁶⁷ Hong Kong, Electronic Transactions Ordinance (Cap 553).

⁹⁶⁸ China, Law of the People's Republic of China on Electronic Signature (中華人民共和國電子簽名法; *zhōng huá rén mín gòng hé guó diàn zǐ qiān míng fǎ*).

⁹⁶⁹ Gitlin (n 704) 169.

Accreditation of Health Organizations and the American Hospital Association. Other states have specifically allowed the use of electronic signatures.⁹⁷⁰ Pennsylvania, for example, has enacted that electronic records and signatures carry the same legal validity as the traditional manual signatures on papers.⁹⁷¹

Without legal interpretation by courts, it may not be easy to predict whether the electronic transactions legislation so enacted in various jurisdictions can be relied upon to establish that an electronic transaction meets the legal requirements for writing and signing.⁹⁷² In *Lamle v Mattel Inc.*,⁹⁷³ one of the questions before the US Court of Appeals for the Federal Circuit was whether an email issued by an employee of the appellee with his name appearing at the end of the electronic messages was a valid writing and signature to satisfy the statutory requirement for a contract to be in writing and 'subscribed by the party to be charged or by the party's agent' as spelt out in the Statute of Frauds in California.⁹⁷⁴ The Court ruled that under California law, such an email satisfied the Statute of Frauds.⁹⁷⁵ In Australia, various states and territories are constitutionally empowered to make their own laws in areas not specifically assigned to the federal government under the Australian Constitution of 1901.⁹⁷⁶ Laws in relation to limitation and electronic transactions fall into the independent legislative power of states and territories. In New South Wales, for example, the Limitation Act 1969 provides that an acknowledgement for the purposes of a cause of action must be in writing and signed by the maker,⁹⁷⁷ and its Electronic Transactions Act 2000 stipulates that if there is a requirement for a person's signature in a transaction, it may be met by an electronic method as long as the method is reliable, the person who has given his or her approval of the transaction is identifiable, and the signature recipient consents.⁹⁷⁸ In *McGuren v Simpson*,⁹⁷⁹ a case in New South Wales, the document in question was a hardcopy printout of the claimant's

⁹⁷⁰ Ibid.

⁹⁷¹ United States, Pennsylvania Statutes, see, for example, §2260.303, §2260.307 and §2260.309.

⁹⁷² Judith McNamara and Kathryn L O'Shea, 'Minimising Legal Risks in Electronic Contracting' (Conference on Collaborative Electronic Commerce Technology and Research, Melbourne, Australia, 2007) [2.3.1].

⁹⁷³ 394 F.3d 1355, 73 U.S.P.Q.2d 1496 (C.A.Fed. (Cal.), 2005) (United States Court of Appeals, Federal Circuit).

⁹⁷⁴ United States, California Civil Code §1624.

⁹⁷⁵ *Lamle v Mattel Inc.* 394 F.3d 1355, 1362 (C.A.Fed. (Cal.), 2005) (United States Court of Appeals, Federal Circuit).

⁹⁷⁶ Australia, Department of Foreign Affairs and Trade, *Legal system* (updated February 2012) <http://www.dfat.gov.au/facts/legal_system.html> accessed 16 September 2012.

⁹⁷⁷ Australia, Limitation Act 1969, New South Wales Consolidated Acts, section 54(4).

⁹⁷⁸ Australia, Electronic Transactions Act 2000, New South Wales Consolidated Acts, section 9(1).

⁹⁷⁹ [2004] NSWSC 35 (Supreme Court of New South Wales).

email bearing a simple name typed in plain text at the end of the email. The Supreme Court of New South Wales held that the electronic communication satisfied the requirements of writing and signature under section 54 of the Limitation Act 1969 of New South Wales, as the claimant's name appeared in the email and she expressly acknowledged in the email an authenticated expression of a prior agreement. In Singapore, in *SM Integrated Transware Ltd v Schenker Singapore (Pte) Ltd*,⁹⁸⁰ a defendant's employee sent out emails to the claimant without appending his name at the bottom of any of the electronic messages, but his name appeared each time at the 'From' column adjacent to the sender's email address. The High Court of Singapore held that an email address, a signature that has been typed onto an email, and in case the email did not contain a typed signature, a name next to the sender's email address at the top of the email are sufficient for the writing and signing purposes of section 6(d) of the Civil Law Act 1994.⁹⁸¹ In the UK, the court's position is different to the ruling of *SM Integrated Transware Ltd* in Singapore. The question before the English court in *Mehta v Pereira Fernandes*⁹⁸² was whether an email bearing an email address but without a signature could satisfy section 4 of the Statute of Frauds Act 1677 that no action against a party is allowed unless the agreement or contract is in writing and signed. The court held that an email is equivalent of a fax or telex number, but the automatic insertion of a sender's email address by an ISP after the email has been transmitted was not sufficient to be considered as a signature to meet section 4 of the 1677 Act. Pelling J said,

My understanding is that [the Electronic Communications Act 2000 (UK)] was enacted in order to give effect to the Directive on European Electronic Commerce (Council Directive 2000/31/EC) ... [T]he Law Commission's view in relation to this Directive is that no significant changes are necessary in relation to statutes that require signatures because whether those requirements have been satisfied can be tested in a functional way by asking whether the conduct of the would be signatory indicates an authenticating intention to a reasonable person.⁹⁸³

⁹⁸⁰ [2005] SGHC 58, [2005] 2 SLR 651 (High Court of Singapore).

⁹⁸¹ Singapore, Civil Law Act 1994 (Chapter 43, Revised Edition).

⁹⁸² [2006] EWHC 813 (Ch), [2006] 1 WLR 1543 (High Court Chancery Division: Manchester).

⁹⁸³ Ibid [31].

Forder commented that both *McGuren v Simpson*⁹⁸⁴ in Australia and *Mehta v Pereira Fernandes*⁹⁸⁵ in the UK did not successfully develop a clear and consistent approach to the judicial interpretation of the electronic transactions legislation and none of them adduced relevant technical or other evidence to prove the appropriateness or reliability of the signature methods used. She has expected that such difficult issues will get sufficient attention when cases go to a senior appellate court.⁹⁸⁶

6.2.2 Patient Data Protection

Medical records receive a higher level of privacy protection than other types of personal information,⁹⁸⁷ as they contain more sensitive personal information than any other single document and patients have the expectation that health practitioners will hold them in confidence.⁹⁸⁸

6.2.2.1 Patient Privacy and Confidentiality in General

‘[C]onfidence is the cousin of trust’, said Megarry J in *Coco v AN Clark (Engineers) Ltd* in the UK.⁹⁸⁹ Confidence signifies the trust between health practitioners and patients,⁹⁹⁰ without which patients may not be willing to disclose relevant personal information to help health practitioners make diagnoses and plan treatments or may even deliberately hide some personal data away. Without such confidence, people may fear that their medical records will be used improperly to ‘deny them important consumer opportunities and benefits.’⁹⁹¹ It was reported that a mother tore away a few pages of her medical records to hide the fact that she had a genetic disease, for fear that such genetically-based health records would affect her

⁹⁸⁴ [2004] NSWSC 35 (Supreme Court of New South Wales).

⁹⁸⁵ [2006] EWHC 813 (Ch), [2006] 1 WLR 1543 (High Court Chancery Division: Manchester).

⁹⁸⁶ Forder (n 948) 426.

⁹⁸⁷ Meenakshi Datta and Karen Owen Dunlop, ‘Privacy of Electronic Health Information’ in Lynn D Fleisher and James C Dechene (eds), *Telemedicine and e-health law*, Release 9 (Law Journal Press, New York [2004] - <2009>) 6-6 §6.01[2].

⁹⁸⁸ Fillmore Buckner, ‘Medical Records’ in S Sandy Sanbar, Marvin H Firestone, Fillmore Buckner, Allan Gibofsky, Theodore R LeBlang, Jack W Snyder, Cyril H Wecht and Miles J Zaremski (eds), *Legal Medicine* (6th edn, Mosby Inc., Pennsylvania, United States 2004) 355.

⁹⁸⁹ [1968] FSR 415, 419, [1969] RPC 41 (High Court Chancery Division).

⁹⁹⁰ General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (effective from 12 October 2009) (General Medical Council, London 2009) 6 [6].

⁹⁹¹ Alan F Westin, ‘How the Public Views Health Privacy: Survey Findings From 1978 to 2005’ as cited in Datta and Dunlop (n 987) 6-66 §6.07.

children's chance to get insurance in the future.⁹⁹²

Patients have a high level of concern about their privacy and confidentiality. A survey in the US in 1999 revealed that 29% of American respondents had 'loss of personal privacy' as their first or second concern, whilst other issues including terrorism and world war only scored 23% at most.⁹⁹³ Privacy rights are considered fundamental in the US. Brandeis J in the Supreme Court of the US in *Olmstead v United States* described the right to privacy as 'the right most valued by civilised people'.⁹⁹⁴ This right was extended by the same court in *Whalen v Roe*,⁹⁹⁵ where the right to privacy was classified into the right against unwanted disclosure of personal matters and the right to making important decisions. In *Jaffee v Redmond*,⁹⁹⁶ the Supreme Court of the US further differentiated the right against unwanted disclosure of personal information into disclosure of physical health and mental health of an individual. In Canada, patient privacy is also treated with high regard. In *Re Axelrod*, the appellant was a bankrupt dentist. The respondent company found that his patient list and files were the most valuable part of his practice and sought a court order that it was entitled to enforce its security against the patient list and files and transfer them to another qualified dentist. The appellant opposed the above request based on a belief that his duty of confidentiality precluded the patient list and files from being valid security. Arbour JA sitting on the Ontario Court of Appeal said, '[T]he Appellant owes a duty to his patients to serve their best interests. "Best interests" are not strictly limited to medical needs, but also encompass privacy and confidentiality.'⁹⁹⁷

6.2.2.1.1 Ethical and Legal Duty of Confidentiality

Since the time of Hippocrates the ethical principles of confidentiality have been closely connected to medical professionals.⁹⁹⁸ On top of a positive duty to exercise reasonable care and skill in the discharge of their duties, health practitioners

⁹⁹² Robert Klitzman, 'The Quest for Privacy Can Make Us Thieves' *The New York Times* (New York, 9 May 2006) <<http://www.nytimes.com/2006/05/09/health/09essa.html>> accessed 31 May 2012.

⁹⁹³ Wall Street Journal/ABC poll of 16 September 1999, as cited in United States, Department of Health and Human Services, 'Standards for Privacy of Individually Identifiable Health Information' (2000) 65(250) Federal Register 82465.

⁹⁹⁴ 277 U.S. 438, 478, 48 S.Ct. 564, 572, 72 L.Ed. 944, 956 (U.S., 1928) (Supreme Court of the United States).

⁹⁹⁵ 429 U.S. 589, 599-600, 97 S.Ct. 869, 876 (U.S.N.Y., 1977) (Supreme Court of the United States).

⁹⁹⁶ 518 U.S. 1, 116 S.Ct. 1923, 135 L.Ed.2d 337 (U.S.Ill., 1996) (Supreme Court of the United States).

⁹⁹⁷ (1994), 29 CBR (3d) 74, 20 OR (3d) 133, 8 PPSAC (2d) 1, 119 DLR (4th) 37, 17 BLR (2d) 161, 74 OAC 376, 50 ACWS (3d) 897 (Ontario Court of Appeal), [10].

⁹⁹⁸ Benedict A Stanberry (n 568) 21 [4.3].

like other professionals are also subject to restrictions on their conduct, which can be classified into three categories: fiduciary obligations such as a core duty of undivided loyalty, undue influence that no abuse of patients' confidence for a return of material advantage favouring the practitioners, and confidentiality that a health practitioner is not allowed generally to disclose patients' confidential information acquired in the healthcare processes.⁹⁹⁹ Health practitioners' duty of confidentiality comes from three distinct sources, namely contractual, equitable and moral duties, and governs the relationship with patients.¹⁰⁰⁰ All health practitioners should abide by their duty of confidentiality, though their ethical and professional duties may not be expanded into a legal duty in all occasions.¹⁰⁰¹ In the US, the Supreme Court of South Carolina in *Evans v Rite Aid Corporation* held that pharmacists do not have a statutory or common law duty of confidentiality. Toal J said, '[A]lthough the Code of Ethics of the American Pharmaceutical Association may be a potential source of guidance on a pharmacist's duty of care generally ... No South Carolina case has ever recognized such a [statutory or common law duty of confidentiality], nor are we aware of any other jurisdiction that has done so.'¹⁰⁰² Irrespective of whether there is any legal duty of confidentiality, professional entities in different jurisdictions such as the UK,¹⁰⁰³ South Africa,¹⁰⁰⁴ and Hong Kong¹⁰⁰⁵ have required their members to observe the ethical and professional duty of confidentiality. In the UK, the Medical Act¹⁰⁰⁶ empowers the General Medical Council to advise their members on professional conduct, standards and ethics. Accordingly, the Council has promulgated that doctors have to respect patients' privacy and the right to confidentiality to fulfill their roles in the doctor-patient relationship.¹⁰⁰⁷ In South Africa, the Health Professions Council requests health practitioners not to disclose patient information without good and

⁹⁹⁹ Powell, Stewart and Jackson (eds) (2007) (n 391) 9 [2-005] – 10 [2-006].

¹⁰⁰⁰ Kieran Doran, 'Medical confidentiality: the role of the doctrine of confidentiality in the doctor-patient relationship' (1997) 3 *Medico-Legal Journal of Ireland* 21, 21.

¹⁰⁰¹ *Evans v Rite Aid Corporation* 324 S.C. 269, 478 S.E.2d 846 (S.C., 1996) (Supreme Court of South Carolina).

¹⁰⁰² *Ibid* 324 S.C. 269, 273, 478 S.E.2d 846, 848.

¹⁰⁰³ General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (2009) (n 990).

¹⁰⁰⁴ Health Professions Council of South Africa, *Guidelines for Good Practice in the Health Care Professions: General Ethical Guidelines for the Health Care Professions* (Health Professions Council, Pretoria 2008).

¹⁰⁰⁵ Medical Council of Hong Kong (2009) (n 649).

¹⁰⁰⁶ United Kingdom, Medical Act 1983, section 35.

¹⁰⁰⁷ General Medical Council of the United Kingdom, *Good Medical Practice* (effective from 13 November 2006) (General Medical Council, London 2006) 15 [21]

overriding reasons.¹⁰⁰⁸ In Hong Kong, the Nursing Council has enacted eight aspects of professional conduct for nurses to discharge their duty in a professional capacity, one of which is to ask nurses to keep personal information obtained in a professional capacity confidential.¹⁰⁰⁹ International organizations have also advocated the same for years. The International Code of Medical Ethics adopted by the World Medical Association stipulates that physicians have a duty to respect patients' rights to confidentiality.¹⁰¹⁰ Similarly, the Declaration of Geneva requires doctors to respect 'the secrets that are confided in [doctors], even after the patient has died'.¹⁰¹¹ The duty of confidentiality continues after the death of a patient.¹⁰¹² In the UK, in *Lewis v Secretary of State for Health*,¹⁰¹³ the applicant doctor asked the court's leave to disclose the medical records of certain deceased patients to a public inquiry. The court recognized that a doctor's duty of confidentiality towards a patient continued after the patient's death, but held that the public interest in the disclosure of the medical records outweighed the public interest in maintaining their confidentiality. O'Neill said that these ethical standards serve as a guide for health practitioners to judge particular situations that may be developed in the course of their professional practices.¹⁰¹⁴

In addition to health practitioners' ethical obligations to maintain confidentiality, patient privacy is further protected legally in some jurisdictions.¹⁰¹⁵ In the US, most of the states, if not all, recognize privacy as a common law tort right and/or a statutory right, with some states such as California and Tennessee treating it as a state constitutional right.¹⁰¹⁶ In the UK, the English law has long recognized such a duty of confidence, which was treated as equitable in nature until *Prince Albert v Strange*¹⁰¹⁷ laid the foundation stone of the modern law of the duty of

¹⁰⁰⁸ Health Professions Council of South Africa (n 1004) 7 [5.4].

¹⁰⁰⁹ Nursing Council of Hong Kong, *Code of Professional Conduct and Code of Ethics for Nurses in Hong Kong* (2002) 3.

¹⁰¹⁰ Lastly amended in October 2006 at the 57th General Assembly of the World Medical Association, Pilanesberg, South Africa.

¹⁰¹¹ Lastly amended in May 2006 at the 173rd Council Session of the World Medical Association, Divonne-les-Bains, France.

¹⁰¹² General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (2009) (n 990) 28 [70].

¹⁰¹³ [2008] EWHC 2196, [2008] LS Law Medical 559, (2008) 105(38) LSG 23 (High Court Queen's Bench).

¹⁰¹⁴ O'Neill, 'Matters of Discretion - The Parameters of Doctor/Patient Confidentiality' (1995) 1(3) Medical Legal Journal of Ireland 94.

¹⁰¹⁵ Gitlin (n 704) 167.

¹⁰¹⁶ United States, Department of Health and Human Services (2000) (n 993) Federal Register 82464.

¹⁰¹⁷ (1849) 2 De G & Sm 652, 64 ER 293 (Court of Chancery).

confidence.¹⁰¹⁸ In *Attorney-General v Guardian Newspapers (No. 2)*, the House of Lords said,

... a duty of confidence arises when confidential information comes to the knowledge of a person (the confidant) in circumstances where he has notice, or is held to have agreed, that the information is confidential, with the effect that it would be just in all the circumstances that he should be precluded from disclosing the information to others.¹⁰¹⁹

Staff working with health practitioners who provide support care and receive personal information are also required to abide by the duty of confidentiality, irrespective of whether they have contractual or professional obligations to protect confidentiality. Professional bodies such as the General Medical Council of the UK¹⁰²⁰ and the Health Professional Council of South Africa¹⁰²¹ have stipulated this requirement for their members to follow.

6.2.2.1.2 Exceptions to the Duty of Confidentiality

Although the right to privacy will be infringed when a confidant discloses a confider's private information without the latter's consent, confidentiality is not an absolute duty per se.¹⁰²² Boreham J in *Hunter v Mann* in the UK said, 'In common with other professional men for instance a priest ... [a] doctor is under a duty not to disclose [voluntarily], without the consent of his patient, information which he, the doctor, has gained in his professional capacity, save ... in very exceptional circumstances.'¹⁰²³ Ethical, statutory and common law exceptions to the duty of confidentiality are available.¹⁰²⁴ At common law, the exception to the duty of confidentiality was originally narrowly applied to the defence of iniquity on the basis

¹⁰¹⁸ Powell, Stewart and Jackson (eds) (2007) (n 391) 94 [2-157].

¹⁰¹⁹ [1990] 1 AC 109, 281 (House of Lords) (Lord Goff).

¹⁰²⁰ General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (2009) (n 990) 13 [28].

¹⁰²¹ Health Professions Council of South Africa (n 1004) 3 [3.3].

¹⁰²² General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (2009) (n 990) 6 [8].

¹⁰²³ [1974] QB 767, 772, [1974] 2 All ER 414 (Divisional Court).

¹⁰²⁴ Lena A Sanci, Susan M Sawyer, Melissa S-L Kang, Dagmar M Haller and George C Patton, 'Confidential health care for adolescents: reconciling clinical evidence with family values' (2005) 183(8) *The Medical Journal of Australia* 410, 412.

that one cannot be made ‘the confidant of a crime or a fraud’.¹⁰²⁵ Following these years’ development, exceptions have been extended to other circumstances. One of the exceptions is that if it is in the public interest, confidential patient information may be disclosed without consent. In the UK, the Court of Appeal in *Lion Laboratory Ltd v Evans*¹⁰²⁶ held that with a view to a conflict between two public interests, the defence of disclosure in the public interest did not depend on any ‘iniquity’ of the plaintiffs but the defendants had to satisfy the court that there was a serious defence of public interest that might succeed at the trial and did not have to show that the plaintiffs were guilty of iniquitous conduct. Griffiths LJ ended up with a word of caution, ‘[T]here is a world of difference between what is in the public interest and what is of interest to the public.’¹⁰²⁷ In *W v Egdell*,¹⁰²⁸ the claimant was a paranoid schizophrenic and had a history of killing five people and wounding another two. The defendant psychiatrist evaluated the claimant’s mental condition ten years later to assess his application for eventual release or transfer to a less secure facility. The defendant gave a negative report and the lawyers withdrew the claimant’s application. Realizing that the claimant’s hospital and the review tribunal had not seen the report, the defendant sent a copy to the hospital for information and onward transmission to the tribunal. The claimant claimed that the defendant breached his duty of confidentiality. The Court of Appeal held that the public interest in protecting other people against violent acts overrides the public interest in maintaining the confidentiality of patient information. Public interest was also discussed in *D v National Society for the Prevention of Cruelty to Children*, where Lord Edmund-Davies in the House of Lords said,

where (i) a confidential relationship exists (other than that of lawyer and client) *and* (with emphasis) (ii) disclosure would be in breach of some ethical or social value involving the public interest, the court has a discretion to uphold a refusal to disclose relevant evidence provided it considers that, on balance, the public interest would be better served by excluding such evidence ... The sole touchstone is the public interest, and not whether the party from whom disclosure is sought was acting under a

¹⁰²⁵ *Gartside v Outram* (1856) 26 LJ Ch 113, 114 (Wood V-C).

¹⁰²⁶ [1985] QB 526, [1984] 2 All ER 417 (Court of Appeal).

¹⁰²⁷ *Ibid* [1985] QB 526, 553.

¹⁰²⁸ [1990] 2 WLR 471, [1990] 1 All ER 835 (Court of Appeal).

“duty” – as opposed to merely exercising “powers.”¹⁰²⁹

In addition to the prevention of iniquitous conduct and the consideration of public interests, there are other exceptional examples to the duty of confidentiality, including but not limited to implied consent, emergency situations, reporting of communicable diseases, court orders/statutory provisions, and medical research. Implied consent is defined as ‘that which arises by reasonable inference from the conduct of the patient’,¹⁰³⁰ and is usually applied to a health practitioner’s sharing of patient information with other disciplines of health professionals. In the UK, the General Medical Council provides a guideline as follows:

Most patients understand and accept that information must be shared within the healthcare team in order to provide their care. [Doctors] should make sure information is readily available to patients explaining that, unless they object, personal information about them will be shared within the healthcare team ...¹⁰³¹

When patients have given consent to the release of their confidential information, health practitioners no longer bear any obligation of confidence, but it is important for health practitioners to ensure that patients have been fully informed of the consequences of the release, that they have a freedom to give it, and that the use of patient’s confidential information does not exceed what has been consented.¹⁰³² To establish the existence of patients’ implied consent to disclosure, ‘mere convenience is insufficient justification’.¹⁰³³ It is necessary to prove that patients are aware of the disclosure and are given a chance to object to it.¹⁰³⁴ In emergency situations, health practitioners are also allowed to disclose patients’ health information. In an emergency and where it is impracticable to obtain a patient’s consent, e.g. he or she is unconscious, a health practitioner may disclose the patient’s confidential information

¹⁰²⁹ [1978] AC 171, 245-246, [1977] 1 All ER 589 (House of Lords).

¹⁰³⁰ Arnold J Rosoff, as cited in Amitai Etzioni, ‘Medical Records: Enhancing Privacy, Preserving the Common Good’ (1999) 29(2) The Hastings Center Report 14, 19.

¹⁰³¹ General Medical Council of the United Kingdom, *Confidentiality: The duties of a doctor registered with the General Medical Council* (2009) (n 990) 12 [25].

¹⁰³² Doran (n 1000) 23.

¹⁰³³ Donal Manning, ‘Commentary: Don’t waive consent lightly – involve the public’ (2002) 324(7347) British Medical Journal 1213, 1213.

¹⁰³⁴ Emily Jackson (n 325) 337.

if it is in the patient's best interests to do so and the amount of information disclosed is minimally necessary.¹⁰³⁵ As for reporting of infectious diseases, the Prevention and Control of Disease Regulation of Hong Kong, for instance, requires a doctor to report any suspected infection of certain diseases to the government and to furnish a health officer, for the purpose of investigation, with any information about the case.¹⁰³⁶ To further protect patient privacy and confidentiality, there have been voices that patients' explicit consent should be sought before health practitioners send out identifiable patient data to third parties even for public health surveillance purposes.¹⁰³⁷ A further exception is court orders and statutory provisions. In legal proceedings, courts may order a party to disclose medical reports to the other parties in the dispute. In Ireland, the Court and Court Officers Act 1995¹⁰³⁸ empowers the Superior Courts Rules Committee or the Circuit Court Rules Committee, along with the Minister for Justice, to make rules requiring any party to a personal injury lawsuit in the High Court or Circuit Court to disclose medical reports to the opposing party without requiring an application to the court. In Victoria in Australia, s. 180 of the Children, Youth and Families Act 2005 (Vic) provides a statutory exception, stating that information about a child in the care of a person other than the parent cannot be disclosed except for the purpose of providing appropriate care for the child.

The issue of using patient information for medical research is a bit tricky. Researchers may not take it for granted that patients have given implied consent for their access to and use of confidential patient information. In the UK, a survey involving 3,429 patients with angina and asthma showed that 335 (9.8%) refused consent to the collection of data from their clinical records for research purpose.¹⁰³⁹ Baker and colleagues suggested researchers seek individual consent prior to the stage of data collection from medical records, except where a research ethics committee has waived such requirement for pressing and justifiable reasons.¹⁰⁴⁰ However, the approval of ethics committees does not necessarily make research free from trouble. The *Professor Simon Shorvon* case in Singapore gives a vivid illustration. This was

¹⁰³⁵ Doran (n 1000) 23.

¹⁰³⁶ Cap 599A, sections 4 and 5.

¹⁰³⁷ Chris Verity and Angus Nicoll, 'Consent, confidentiality, and the threat to public health surveillance' (2002) 324(7347) *British Medical Journal* 1210, 1211.

¹⁰³⁸ Section 45(1)(a)(i).

¹⁰³⁹ Richard Baker, Christopher Shiels, Keith Stevenson, Robin Fraser and Margaret Stone, 'What proportion of patients refuse consent to data collection from their records for research purposes?' (2000) 50(457) *British Journal of General Practice* 655.

¹⁰⁴⁰ *Ibid* 655-656.

not a court case but an arguable professional case in 2002, with a central question on whether a researcher, after getting the approval of the organizational ethics committees and a national research grant, could access medical records and alter patients' medication without notifying the relevant patients' attending doctors and without letting the patients know the purpose of access to their medical information.¹⁰⁴¹ The researcher was dismissed and fined for serious ethical violations in 2003. As the researcher was subsequently based in London, the Singapore Medical Council pursued the case before the General Medical Council in the UK, but the latter cancelled plans to hold a public inquiry, declaring that the researcher 'did not fall short of any expected standards'.¹⁰⁴²

6.2.2.2 Patient Privacy and Confidentiality in Telemedicine

Telemedicine resembles electronic commerce in the way that business entities and consumers both require confidence in electronic transactions. They expect that no modification or interception will occur in the transactions, security online is not compromised, and the transactions are safe from cyber theft and fraud.¹⁰⁴³ Similarly, in telemedicine, people are concerned about security, privacy and confidentiality in the electronic consultation processes.¹⁰⁴⁴

Privacy is one of the legal issues preventing the growth of telemedicine,¹⁰⁴⁵ as the technologies used in the Internet such as the Internet Protocol are designed for 'open' communication and provide no protection for confidential information.¹⁰⁴⁶ This open design poses patient privacy risks beyond those in traditional healthcare settings. Privacy risks come from two sources, namely (a) user access and authentication, and (b) transmission.¹⁰⁴⁷ In the area of access and authentication, patients' worries about inappropriate access to and even usage of their medical

¹⁰⁴¹ Owen Dyer, 'Specialist ousted in research row' (2003) 326(7394) *British Medical Journal* 839.

¹⁰⁴² Hui Leng Tan, 'SMC asks medical journal The Lancet: Why no right of reply?' *Channel NewsAsia Singapore* (Singapore, 30 August 2007)

<<http://www.channelnewsasia.com/stories/singaporelocalnews/view/296856/1/.html>> accessed 12 May 2012.

¹⁰⁴³ Ong (n 577) 101.

¹⁰⁴⁴ Lennart Magnusson and Elizabeth Jane Hanson, 'Ethical issues arising from a research, technology and development project to support frail older people and their family carers at home' (2003) 11 *Health and Social Care in the Community* 431, 433.

¹⁰⁴⁵ Caryl (n 130) 179.

¹⁰⁴⁶ Dixie B Baker and Daniel Masys, 'PCASSO: Vanguard in Patient Empowerment' in Rosemary Nelson and Marion J Ball (eds), *Consumer Informatics: Applications and Strategies in Cyber Health Care* (Springer-Verlag, United States 2004) 67.

¹⁰⁴⁷ Datta and Dunlop (n 987) 6-66 §6.07.

information are no longer an academic topic, as health data may be downloaded for malicious or inquisitive purposes.¹⁰⁴⁸ In *HKSAR v Tsun Shui Lun*¹⁰⁴⁹ in Hong Kong, the ex-Secretary for Justice underwent surgery. An assistant of the concerned hospital was convicted of violating her privacy, as he got access to her electronic medical records improperly and made her clinical conditions public. To better safeguard patient data from unauthorized access, health institutes have to be equipped with necessary safety measures. In an American hospital, a computerized ‘monitor’ function has been developed in its EHR system to serve as a watchdog. Health practitioners who have set up this function for particular medical records will be prompted immediately through electronic messages when unauthorized readers try to get access to those records.¹⁰⁵⁰ On top of system safeguards, Chiang and Starren have also suggested that those non-medical personnel such as telemedical technicians who are not normally involved in traditional medical consultations should abide by privacy restrictions set by health institutes.¹⁰⁵¹

In connection to real-time interactive consultations or electronic ‘store-and-forward’ transmissions of medical information such as X-ray records, health practitioners providing telemedical services have to pay attention to how medical records or their medical opinions will be transmitted. In an unreported case in California, *Chabra v Southern Monterey County Memorial Hospital*, the plaintiff radiologist alleged that others ‘use[d] teleradiology excessively to transmit non-emergency radiological films to his office away from [a hospital], resulting in poorer film quality and poorer correlation between radiological stud[ies] and pathological results ...’¹⁰⁵² This case has illustrated that improper transmissions of health information will interrupt health services. Also, safe transmissions of accurate information to the other end of a telemedical consultation are crucial for diagnoses. Another example has been reported that an inaccurate transmission of the colour of a lesion could lead to a wrong diagnosis in teledermatology.¹⁰⁵³ In the US, the Standards for Privacy of Individually Identifiable Health Information enacted under

¹⁰⁴⁸ United States, Department of Health and Human Services (2000) (n 993) Federal Register 82465.

¹⁰⁴⁹ [1999] 3 HKLRD 215, [1999] 2 HKC 547 (Court of First Instance).

¹⁰⁵⁰ C Safran, D Z Sands and D M Rind, ‘Online Medical Records: A Decade of Experience’ (1999) 38(4-5) *Methods of Information in Medicine* 308, 312.

¹⁰⁵¹ Michael F Chiang and Justin Starren, ‘Telemedicine and HIPPA’ as cited in Datta and Dunlop (n 987) 6-67 §6.07.

¹⁰⁵² Not Reported in F.Supp., 1994 WL 564566, 6 (N.D.Cal., 1994) (District Court of California).

¹⁰⁵³ Earl V Dunn, David W Conrath, William G Bloor and Barbara Tranquada, ‘An Evaluation of Four Telemedicine Systems for Primary Care’ (1977) 12(1) *Health Services Research* 19, 28-29.

the Health Insurance Portability and Accountability Act 1996 provide protection for ‘protected health information’¹⁰⁵⁴ held or transmitted by statutorily defined health plans, health care clearinghouses, health care providers or their business associates, irrespective of whether the health information is stored in electronic, paper, or oral formats. The Standards for Privacy of Individually Identifiable Health Information require health institutes to maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information in violation of the stipulated privacy rules and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure.¹⁰⁵⁵ In Europe, a number of directives applicable to telemedicine have been enacted.¹⁰⁵⁶ For instance, the Council Directive 95/46/EC applies to non-public communications services¹⁰⁵⁷ and stipulates requirements in relation to the processing of personal data and protection of privacy for telecommunication services.¹⁰⁵⁸ The Council Directive 2002/58/EC is for public communications services and spells out requirements for providers of electronic communications services to ensure the confidentiality of communications¹⁰⁵⁹ and safeguard the security of their services.¹⁰⁶⁰

6.2.2.2.1 Email Communications

Email communication as one of the simplest and commonest form of access to the Internet may radically change the culture of healthcare delivery,¹⁰⁶¹ but it is also ‘the most problematic practice’¹⁰⁶² of telemedicine. In the legal context, email is unique as ‘it is part of telemedicine law, part of medical records law, has many of the legal attributes of the telephone in health care law, and mimics the

¹⁰⁵⁴ 45 CFR §160.103.

¹⁰⁵⁵ 45 CFR §164.530(c).

¹⁰⁵⁶ European Commission (2008) (n 778) 9-10.

¹⁰⁵⁷ European Union, Directive 2002/58/EC of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), Preamble, paragraph 10.

¹⁰⁵⁸ European Union, Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, article 1.

¹⁰⁵⁹ European Union, Directive 2002/58/EC of 12 July 2002 (n 1057) Preamble, paragraph 21.

¹⁰⁶⁰ Ibid, Preamble, paragraph 20.

¹⁰⁶¹ Janet C Struber, ‘An Introduction to Telemedicine and Email Consultations’ (2004) 2(3) The Internet Journal of Allied Health Sciences and Practice 1, 2.

¹⁰⁶² Ewell (n 769) 69.

evidence problems of traditional mail.’¹⁰⁶³ From a perspective of risk management, email communications between health practitioners and patients pose privacy and security risks. Emails resemble ‘a postcard rather than a letter’ in that they are open to their carriers and it is easier to send an email to a wrong address than post a regular mail in traditional postage.¹⁰⁶⁴ In telemedicine, anyone who has had access to a health practitioner’s email account may alter or delete the email records or even give responses to a patient without notice to the practitioner.¹⁰⁶⁵ There are also other concerns in the use of emails, including the authenticity of the parties involved, the validity of the information exchanged, the disparities between both parties’ expectations, the standard of care, and the preservation of the physician-patient relationship, etc.¹⁰⁶⁶

Cautions from professional bodies to health practitioners against the use of emails to make communication with patients have been loud and clear. In the US, the Code of Medical Ethics of the American Medical Association states that in the absence of a prior relationship, a physician should not make use of email communications to establish a new legal relationship with patients, and emails should only help strengthen other personal communications with patients.¹⁰⁶⁷ The California Academy of Family Physicians has warned its members to give serious consideration if they plan to exchange emails with their patients.¹⁰⁶⁸ The Medical Council of Hong Kong also preferred direct consultation to teleconsultation.¹⁰⁶⁹ Kane and Sands developed a set of guidelines for using email communications with patients, examples of which include asking patients to give written informed consent before commencement of an electronic relationship, not to use emails for urgent matters, notifying patients about privacy issues, asking patients to put the category of a

¹⁰⁶³ Fillmore Buckner, ‘Electronic Mail Communication with Patients’ in Sanbar and others (eds) (2004) (n 988) 417.

¹⁰⁶⁴ Ibid 418.

¹⁰⁶⁵ Hodge, Gostin and Jacobson (n 572) 1467.

¹⁰⁶⁶ Amy M Bovi, ‘Ethical Guidelines for Use of Electronic Mail Between Patients and Physicians’ (2003) 3(3) *The American Journal of Bioethics* W43, W44.

¹⁰⁶⁷ American Medical Association, *AMA’s Code of Medical Ethics*, Opinion 5.026 – The Use of Electronic Email, Opinion 5.026(1) <<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>> accessed 20 May 2012.

¹⁰⁶⁸ The California Academy of Family Physicians, *Making the Most of Physician-Patient Email* (Executive Summary, 2000) 1 <<http://www.familydocs.org/assets/Publications/Monographs/EmailMonograph.pdf>> accessed 27 May 2012.

¹⁰⁶⁹ Medical Council of Hong Kong, IT Committee, *Recommendations on Doctors’ Internet Home Page*, attached as Appendix A to Medical Council of Hong Kong, *Guidelines on Internet Homepages and Telemedicine* (a letter referenced MC 4/4/A X dated 30 June 2000) 2.

transaction in the subject line for easy onward transmission to appropriate personnel, etc.¹⁰⁷⁰ Although the guidelines of Kane and Sands were proposed more than a decade ago, they are still practical and in line with current professional guidance issued by other medical societies. The Texas Medical Association has provided similar guidelines to their members in the areas of checking the identity of online correspondents, protecting patient data confidentiality, mitigating the risk of unauthorized access, obtaining patient consent prior to the initiation of online communication, and using email communications only after the establishment of a traditional doctor-patient relationship, etc.¹⁰⁷¹ It is also important for health practitioners and institutes to have well-drafted informed consent and email guidelines in place.¹⁰⁷²

Emails are admissible to court as evidence. In a criminal case in the US, the Court of Appeals of Virginia in *Bloom v Commonwealth of Virginia*¹⁰⁷³ held that messages received over the Internet are admissible against the sender if the evidence establishes the identity of the sender. Email evidence must be relevant, material, integral and authentic for admission to court.¹⁰⁷⁴ To enhance the reliability of email as evidence in court, on top of any legal requirements, health practitioners and institutes may also consider compliance with good industry practice such as the Code of Practice for Legal Admissibility and Evidential Weight of Information Stored Electronically issued by the British Standards Institution,¹⁰⁷⁵ which provides a framework to assess the reliability of electronic evidence. Compliance with this Code does not automatically make electronically stored documents admissible but it is likely to strengthen any claim of reliability. Non-compliance with the Code of Practice for Legal Admissibility and Evidential Weight of Information Stored Electronically or other good industrial practices may be subject to an opponent's attacks in court. Such attacks may be based on an allegation that the reliability, integrity and authenticity of emails are not protected by security measures such as personal access codes, encryption, and audit trails, which provide better protection for

¹⁰⁷⁰ Beverley Kane and Daniel Z Sands, 'Guidelines for the Clinical Use of Electronic Mail with Patients' (1998) 5(1) Journal of the American Medical Informatics Association 104.

¹⁰⁷¹ Texas Medical Association, *Patient-Physician Electronic Communication* (2010) <<http://www.texmed.org/templateprint.aspx?id=2480>> accessed 27 May 2012.

¹⁰⁷² Buckner, 'Electronic Mail Communication with Patients' (n 1063) 422.

¹⁰⁷³ 34 Va.App. 364, 370, 542 S.E.2d 18, 20 (Va.App. 2001) (Court of Appeals of Virginia).

¹⁰⁷⁴ Jie Zheng, 'Email Evidence Preservation: How to Balance the Obligation and the High Cost' (2009) 14(2) Lex Electronica 1, 6.

¹⁰⁷⁵ BIP 0008:2004.

data from fraud, abuse, and unauthorized access and disclosures.¹⁰⁷⁶ Among these security measures, encryption is ‘a data security technique in which digital information is recorded to make the bit stream unreadable to others who do not have the necessary system for restoring the data into its original form.’¹⁰⁷⁷ Audit trail is another important tool to help demonstrate that patients’ information stored in computerized format has or has not been amended,¹⁰⁷⁸ and it has been generally recognized that unless adequate audit trails are available, it is technically difficult to trace who has disclosed patient data through the virtual environment without permission.¹⁰⁷⁹

As far as the technical standard of protection is concerned, telemedicine is subject to constant technological changes.¹⁰⁸⁰ For example, the key length of smart cards which provide electronic signatures for authentication, integration protection and non-repudiation for access to a telemedicine network has been changing over the years.¹⁰⁸¹ In 1999 the then two major web browsers, Netscape and Microsoft Internet Explorer, used 128-bit encryption as the standard,¹⁰⁸² and the general public currently uses security protocols such as Wired Equivalent Privacy (WEP), Wi-Fi Protected Access (WPA) and 802.11i (WPA2) to protect their wireless network, but they are still prone to hacking if the setup and protection are not carefully made.¹⁰⁸³ In the healthcare context, different standards such as the Health Level Seven Clinical Document Architecture, CEN EN 13606 EHRcom and openEHR have been developed.¹⁰⁸⁴ The Health Level Seven International in the US, for instance, has

¹⁰⁷⁶ Hodge, Gostin and Jacobson (n 572) 1466-1467.

¹⁰⁷⁷ Adam William Darkins and Margaret Ann Cary, *Telemedicine and Telehealth* (Springer Publishing Co, New York, United States 2000) 298.

¹⁰⁷⁸ Dunn (ed) (2010) (n 415) 99.

¹⁰⁷⁹ Hodge, Gostin and Jacobson (n 572) 1469.

¹⁰⁸⁰ Eike-Henner W Kluge, ‘Ethical and legal challenges for health telematics in a global world: Telehealth and the technological imperative’ (2011) 80(2) *International Journal of Medical Informatics* e1, e3.

¹⁰⁸¹ François A Allaert and Barry Barber, ‘Law and Standards’ (2000) 60(2) *International Journal of Medical Informatics* 99, 100.

¹⁰⁸² United States, ‘Medicare and Medicaid Programs; Mandatory Use, Collection, Encoding, and Transmission of Outcome and Assessment Information Set (OASIS) for Home Health Agencies’ (1999) 64(117) *Federal Register* (Billing Code 4120-03-C) 32984, 32986.

¹⁰⁸³ Vishal Kumkar, Akhil Tiwari, Pawan Tiwari, Ashish Gupta and Seema Shrawne, ‘Vulnerabilities of Wireless Security protocols (WEP and WPA2)’ (2012) 1(2) *International Journal of Advanced Research in Computer Engineering & Technology* 34.

¹⁰⁸⁴ Marco Eichelberg, Thomas Aden, Jörg Riesmeier, Asuman Dogac and Gokce B Laleci, ‘A Survey and Analysis of Electronic Healthcare Record Standards’ (2005) 37(4) *ACM Computing Surveys* 277, 278.

developed a seven-level framework for standards governing the use of EHR.¹⁰⁸⁵ The existence of various standards affects the interoperability of EHRs including emails. Fortunately, the trend is for these standards to be going towards harmonization and unification.¹⁰⁸⁶

Data integrity is a concern. Emails are susceptible to alteration which the recipients may not discern and this raises a problem as the integrity of the evidence requires that emails as evidence in court should not be modified by non-senders or computer systems intentionally or unintentionally before the recipients receive them.¹⁰⁸⁷ The fact that senders do not always sign their names in email communications causes another legal problem in the identification of senders as discussed in the previous section.

The Internet has also created a new question as to how to judge authenticity.¹⁰⁸⁸ ‘On the Internet, nobody knows you’re a dog’¹⁰⁸⁹ and disembodiment and anonymity enable users to take on new virtual identities that may not have a connection to their real life.¹⁰⁹⁰ Authentication techniques such as passwords, automated identifiers,¹⁰⁹¹ cryptosystems including secret-key based and public-key based systems,¹⁰⁹² and digital signature cryptograph in 3-G mobile communications environment,¹⁰⁹³ etc. are used to verify the identity of a sender or recipient of information.

Users’ misconceptions will also lead to legal confusion about the discoverability and admissibility of emails and other electronic records.¹⁰⁹⁴ One of

¹⁰⁸⁵ Health Level Seven International, ‘Introduction to HL7 Standards’ <<http://www.hl7.org/implement/standards/index.cfm?ref=nav>> accessed 24 May 2012.

¹⁰⁸⁶ Eichelberg and others (n 1084) 307.

¹⁰⁸⁷ Zheng (n 1074) 4.

¹⁰⁸⁸ Nalita James and Hugh Busher, ‘Ethical issues in online educational research: protecting privacy, establishing authenticity in email interviewing’ (2007) 30(1) *International Journal of Research & Method in Education* 101, 107.

¹⁰⁸⁹ A quote from a famous cartoon from the *New Yorker* (5 July 1993), as cited in Chris Reed, *Internet Law: Text and Materials* (2nd edn, Cambridge University Press, Cambridge, United Kingdom 2004) 140.

¹⁰⁹⁰ Michael Hardey, ‘Digital life stories: auto/biography in the information age’ (2004) 12(3) *Auto/Biography* 183, 195.

¹⁰⁹¹ Peter Yellowlees, Jay Shore and Lisa Roberts, ‘Policy: Practice Guidelines for Videoconferencing-Based Telemental Health – October 2009’ (2010) 16(10) *Telemedicine and e-Health* 1074, 1083.

¹⁰⁹² Chang-Kuo Yeh and Wei-Bin Lee, ‘An Overall Cost-effective Authentication Technique for the Global Mobility Network’ (2009) 9(3) *International Journal of Network Security* 227, 227.

¹⁰⁹³ Pijush Kanti Bhattacharjee and Chandan Koner, ‘A Novel Subscriber Message Authentication Technique in 3-G Mobile Communications Using Digital Signature’ (2011) 7(2) *Assam University Journal of Science & Technology: Physical Sciences and Technology* 36.

¹⁰⁹⁴ William DeCoste, ‘Sender Beware - The Discoverability and Admissibility of E-Mail’ (2000) 2(1) *Vanderbilt Journal of Entertainment Law & Practice* 79, 81.

people's wrong beliefs is that deleting emails on their computers means permanent erasure of the emails, but those deleted messages in fact still exist and are recoverable by computer forensic technologies in a manner to meet the courts' requirements.¹⁰⁹⁵ Another problem is that people take a less careful attitude in writing emails than they do when drafting formal correspondences and this attitude leads to potential problems in litigation.¹⁰⁹⁶ There is also a mismatch between the perceived level of confidentiality and reality. People tend to think that their electronic messages are private and that they are entitled to protection from others' intrusion. However, it is not always true. In the US, Cox CJ sitting on the US Court of Appeals for the Armed Forces in *United States v Maxwell* said, '... while a user of an e-mail network may enjoy a reasonable expectation that his or her e-mail will not be revealed to police, there is the risk that an employee or other person with direct access to the network service will access the e-mail, despite any company promises to the contrary.'¹⁰⁹⁷ In *Smyth v Pillsbury Co.*,¹⁰⁹⁸ the District Court of Pennsylvania found that even if employees had a reasonable expectation of privacy, a reasonable person would not consider employers' interception of communications to be a substantial and highly offensive invasion of the employees' privacy.

6.2.2.2.2 Health-Related Websites

In addition to emails, health-related websites are another popular platform of communication between health practitioners and patients, which can be broadly classified into two categories: informational websites which do not provide individualized diagnoses or therapeutic advice to patients and interactive websites.¹⁰⁹⁹ Surveys estimated that the number of health-related websites has been over 70,000¹¹⁰⁰ and in the US alone, about 60 million people checked health-related information.¹¹⁰¹ People get used to accessing these websites for a few main purposes, including searching for health information, joining support groups, interacting with health

¹⁰⁹⁵ Bhanu Prakash Battula, B Kezia Rani, R Satya Prasad and T Sudha, 'Techniques in Computer Forensics: A Recovery Perspective' (2009) 3(2) International Journal of Security 27, 27.

¹⁰⁹⁶ Zheng (n 1074) 4.

¹⁰⁹⁷ 45 M.J. 406, 418 (U.S. Armed Forces, 1996) (US Court of Appeals for the Armed Forces).

¹⁰⁹⁸ 914 F.Supp. 97, 101, 64 USLW 2564 (E.D.Pa, 1996) (District Court of Pennsylvania).

¹⁰⁹⁹ Amy M Bovi and the Council on Ethical and Judicial Affairs of the American Medical Association, 'Use of Health-Related Online Sites' (2003) 3(3) The American Journal of Bioethics W48, W48.

¹¹⁰⁰ Grandinetti (n 856).

¹¹⁰¹ Rainie and Packel (n 657) 7.

practitioners,¹¹⁰² and participating in online medical applications such as smoking cessation.¹¹⁰³ More patients want to get in touch with health practitioners through the Internet and they feel frustrated when the practitioners hesitate to contact them online.¹¹⁰⁴ Health practitioners also make use of health-related websites. Harris Interactive revealed that 89% of physician respondents used the Internet for clinical purposes.¹¹⁰⁵ The American Medical Association found that 30% of physicians established their own websites.¹¹⁰⁶

Like emails, health-related websites provide a means of meeting people's specific needs, but they have also had shortcomings.¹¹⁰⁷ The quality and reliability of health information on the Internet vary considerably and are a very real concern. To name a few examples, inappropriate language, content intensity and presentation of health-related websites may result in patients' misinterpretation, mis-targeting of content, and misrepresentation of source and quality.¹¹⁰⁸ It is problematic for a doctor to give a second medical opinion through a health-related website without seeing a patient or communicating with the patient's treating doctor.¹¹⁰⁹ It is also problematic for a health-related website to make computer-generated responses without obtaining health information from physical examinations.¹¹¹⁰ Non-health practitioners or unqualified persons may disguise themselves as qualified under the protection of the Internet screen to make profits.¹¹¹¹ Surveys found that most information on health-related websites lacked completeness and accuracy.¹¹¹² Some information such as sensational anecdotes and unbalanced views presented by some online support

¹¹⁰² R J W Cline and K M Haynes, 'Consumer health information seeking on the Internet: the state of the art' (2001) 16(6) *Health Education Research* 671, 673.

¹¹⁰³ United States, Smokefree.gov <<http://www.smokefree.gov/>> accessed 14 June 2012.

¹¹⁰⁴ Blumenthal (n 733) 536.

¹¹⁰⁵ *Ibid* 525.

¹¹⁰⁶ American Medical Association, *2002 American Medical Association study on physicians' use of the World Wide Web* (AMA Press, Chicago, United States 2002), as cited in Bovi and the Council on Ethical and Judicial Affairs of the American Medical Association (n 1099) W49.

¹¹⁰⁷ Mike Benigeri and Pierre Pluye, 'Shortcomings of health information on the Internet' (2003) 18(4) *Health Promotion International* 381, 382.

¹¹⁰⁸ J M Roberts and K L Copeland, 'Clinical websites are currently dangerous to health' (2001) 62(2-3) *International Journal of Medical Informatics* 181.

¹¹⁰⁹ Bovi and the Council on Ethical and Judicial Affairs of the American Medical Association (n 1099) W49.

¹¹¹⁰ *Ibid* W50.

¹¹¹¹ Brian Monnich, 'Bringing Order to Cybermedicine: Applying the Corporate Practice of Medicine Doctrine to Tame the Wild Wild Web' (2001) 42(2) *Boston College Law Review* 455, 456.

¹¹¹² Gunther Eysenbach, John Powell, Oliver Kuss and Eun-ryoung Sa, 'Empirical Studies Assessing the Quality of Health Information for Consumers on the World Wide Web: A System Review' (2002) 287(20) *Journal of American Medical Association* 2691.

groups¹¹¹³ were even false or misleading.¹¹¹⁴ Also, some websites contain commercially sponsored activities such as promotion of pharmaceutical products which may subject health practitioners or website owners to a potential conflict of interest.¹¹¹⁵ People's purchase of drugs like Viagra over the Internet may pose a threat to their health due to possible over-dosage, dangerous products, and medicinal interactions, etc.,¹¹¹⁶ in addition to the concern that '[a] prescription that results from little or nothing more than filling out an online form – and many offshore sites don't even require that – is a serious and dangerous corruption of what medicine should be about.'¹¹¹⁷ In the US, without seeing a patient, the defendant doctor residing in Colorado in *Hageseth v Superior Court*¹¹¹⁸ prescribed online drugs to the patient in California after he filled out a questionnaire over the Internet. The patient committed suicide afterwards, and the doctor was charged with a criminal offence of practising medicine in California without a licence in violation of section 2052 of the Business and Professions Code.

To better protect the interests of people using health-related websites, professional entities have made ethical safeguards, seeing self governance as an effective way to protect patient privacy for online health information.¹¹¹⁹ In the US, the Federation of State Medical Boards promulgated five ethical standards in its guidelines for physicians when they run health-related websites, including candour, privacy, integrity, informed consent, and accountability.¹¹²⁰ Also, various accreditation agencies have emerged. Taking the American Accreditation Health Care Commission as an example, its accreditation programme requires health-related websites under accreditation to obtain an affirmative opt-in rather than opt-out

¹¹¹³ RIDE and Information Society, "A Roadmap for Interoperability of eHealth Systems in Support of COM 356 with Special Emphasis on Semantic Interoperability" (A project co-funded by the European Commission within the Sixth Framework Programme) (2006) 161 [4.3.3.7.6].

¹¹¹⁴ Lynn Eaton, 'News Extra: Many Websites Make False Health Claims' (2002) 324(7340) British Medical Journal 756.

¹¹¹⁵ Benigeri and Pluye (n 1107) 383.

¹¹¹⁶ Donald E deKieffer, 'Direct sale of sildenafil (Viagra) to consumers over the Internet' (2000) 342(10) The New England of Journal of Medicine 742.

¹¹¹⁷ Editorial, 'Online Rx: Be careful with Web prescriptions' *American Medical News* (United States, 13 May 2002) <<http://www.ama-assn.org/amednews/2002/05/13/edsa0513.htm>> accessed 16 June 2012

¹¹¹⁸ 150 Cal.App.4th 1399, 59 Cal.Rptr.3d 385 (Cal.App. 1 Dist., 2007) (California Court of Appeal, First District).

¹¹¹⁹ Datta and Dunlop (n 987) 6-58 §6.06.

¹¹²⁰ Federation of State Medical Boards of the United States (2002) (n 533) 3.

mechanism to collect and use personal health information¹¹²¹ and demonstrate their adherence to other accreditation standards. If all are satisfactory, the Commission would give the websites its ‘seal of approval’.¹¹²² To address privacy and security concerns, the American Medical Association requires physicians responsible for the content of health-related websites to ensure that the information is accurate, timely, reliable, and scientifically sound¹¹²³ and provides that physicians involved in such websites must minimize conflict of interest and commercial biases through safeguards for disclosure and honesty in funding and advertising.¹¹²⁴ The American Medical Association also provides doctors with a unique authentication technique called AMA Internet ID to replace passwords for secure Internet transactions.¹¹²⁵

Some health-related websites have included disclaimers to define the website owners’ responsibilities and the intent of the health information provided online.¹¹²⁶ For instance, a health-related website made use of a disclaimer stating that without the benefit of face-to-face encounters or physical examinations, second medical opinions given to patients online may be based on some missing but important health information, and the website strongly advised patients to share the second opinion with their own doctors.¹¹²⁷ Another website uses the following wordings in its disclaimer:

Any information on [the] web site is provided for informational and educational purposes only. If you have or suspect you have a health problem, you should consult your health care provider. The [website owner] shall not be liable for any damages, claims, liabilities, costs or obligations arising from the use or misuse of the material contained in this web site, whether such obligations arise in contract, negligence, equity or statute law.

¹¹²¹ American Accreditation Health Care Commission, *URAC Health Content Provider Guide* (Version 3.0) <https://www.urac.org/STDpdfs/STDGlance_HealthContProv.pdf> accessed 14 June 2012, WS 28 and WS 32.

¹¹²² American Accreditation Health Care Commission, ‘General Questions About URAC Accreditation’ <<https://www.urac.org/healthcare/accreditation/>> accessed 14 June 2012.

¹¹²³ American Medical Association, *AMA’s Code of Medical Ethics* (n 1067) Opinion 5.027(1).

¹¹²⁴ *Ibid* Opinion 5.027(4).

¹¹²⁵ American Medical Association, Report 4 of the Council on Medical Service (A-01), *Medical Care Online* (June 2001) 9.

¹¹²⁶ Bovi and the Council on Ethical and Judicial Affairs of the American Medical Association (n 1099) W50.

¹¹²⁷ *Ibid* W49.

[The website owner] has no editorial control over the websites which are linked and takes no responsibility for their content.¹¹²⁸

While it seems that such a disclaimer may protect the institutional interests of health-related websites to some extent, the use of disclaimers needs careful consideration. Quan has cautioned that if a computerized medical record ends with a remark of ‘this is a computer generated record that requires no signature’ or ‘dictated but not read’, a health practitioner is unlikely to gain the court’s sympathy as he or she is too busy to read and sign a medical record.¹¹²⁹ Bovi has also alerted that health practitioners and institutes may not escape their duty owed to patients and their responsibility to provide reliable and accurate information.¹¹³⁰

6.2.2.2.3 Electronic Health Records

Medical records are important evidence and are referred to not only in alleged medical adverse events to help assess if health practitioners have discharged their duty of care reasonably in the course of medical diagnoses and treatments of patients,¹¹³¹ but also in other legal proceedings such as criminal cases. In Singapore, the Criminal Procedure Code empowers the police to request health practitioners to produce ‘a document or other thing ... necessary or desirable for any investigation ...’¹¹³² In the UK, the House of Lords in *Toohey v Metropolitan Police Commissioner* held that medical evidence should be allowed for a defendant to prove the hysterical and unstable nature of the alleged victim of an assault. Lord Pearce said, ‘Medical evidence is admissible to show that a witness suffers from some disease or defect or abnormality of mind that affects the reliability of his

¹¹²⁸ Regional Health Authority of Central Manitoba Inc. of Canada, ‘Disclaimer’ <<http://www.rha-central.mb.ca/disclaimer.php>> accessed 15 June 2012.

¹¹²⁹ Yeo Khee Quan, ‘Medical Records and Confidentiality’ in Quan and others (n 324) 212 [6.10] and 213 [6.15].

¹¹³⁰ Bovi and the Council on Ethical and Judicial Affairs of the American Medical Association (n 1099) W50.

¹¹³¹ Kuan-Ling Shen, ‘The Application of Spoliation Evidence Principle in the Medical Malpractice Claim’ (2009) 38(1) National Taiwan University Law Journal 163 (沈冠伶, ‘證明妨礙法理在醫療民事責任訴訟之適用’ (2009) 38(1) 台大法學論叢 163; *shěn guān líng*, ‘zhèng míng fǎng ài fǎ lǐ zài yī liáo mín shì zé rèn sù song zhī shì yòng’ (2009) 38(1) *tái dà fǎ xué lùn cóng* 163).

¹¹³² Cap 68, section 20.

evidence.¹¹³³ The court may also accord more weight to written medical records than to any witness' memory.¹¹³⁴

Who owns a medical record? A mother with a genetic disease who tore away some of her medical records for the sake of her children being able to get insurance in the future argued, 'The information belongs to me ... It's mine.'¹¹³⁵ There is a view that the legal ownership of a paper medical record belongs to the patient as far as the doctor concerned has not interpreted such a 'verbatim',¹¹³⁶ and the ownership of health practitioners and/or institutes is only a limited primary right that is custodial in nature.¹¹³⁷ At common law, patients do not have an absolute right to their medical records.¹¹³⁸ In *Breen v Williams*,¹¹³⁹ the High Court of Australia unanimously held that under the common law, a patient does not have any right of access to inspect and or obtain copies of his or her medical records. In Canada, the Supreme Court of Canada in *McInerney v MacDonald*¹¹⁴⁰ ruled differently that in the absence of relevant legislation, a patient had a basic and continuing interest in the use of the information and in controlling access to medical records which contained information that was acquired and recorded on behalf of the patient. The UK has taken a middle position. In *R v Mid Glamorgan Family Health Services Authority Ex p. Martin*, the trial court held that patients had rights to see their medical records only when the Data Protection Act 1984 (UK) or the Access to Health Records Act 1990 (UK) so provided. If there had been a common law right of access, it would have been subject to a doctor's judgement on what could be disclosed without causing harm.¹¹⁴¹ Upon appeal the Court of Appeal affirmed the trial judge's ruling and held that a health institute, as the owner of medical records, may deny patients' access to them if it is in their best interests to do so.¹¹⁴² In fact, doctors' views as to whether patients can see their medical records vary and there are two schools of thought. The

¹¹³³ [1965] AC 595, 609, [1965] 1 All ER 506 (House of Lords).

¹¹³⁴ Quan, 'Medical Records and Confidentiality' (n 1129) 210 [6.4].

¹¹³⁵ Klitzman (n 992).

¹¹³⁶ Quan, 'Medical Records and Confidentiality' (n 1129) 237 [6.167].

¹¹³⁷ United States, Office of Technology Assessment, *Medical Privacy Report* (Washington DC, 1993) Chapter 3 Computerized Health Care Information.

¹¹³⁸ Quan, 'Medical Records and Confidentiality' (n 1129) 219 [6.63].

¹¹³⁹ [1995] HCA 63, (1996) 186 CLR 71, 43 ALD 481, 70 ALJR 772, 138 ALR 259 (High Court of Australia).

¹¹⁴⁰ (1992), 7 CPC (3d) 269, 137 NR 35, [1992] 2 SCR 138, 93 DLR (4th) 415, 12 CCLT (2d) 225, 126 NBR (2d) 271, 317 APR 271, JE 92-917, EYB 1992-67321 (Supreme Court of Canada).

¹¹⁴¹ [1993] PIQR P426, [1994] COD 42 (High Court Queen's Bench).

¹¹⁴² *R v Mid Glamorgan Family Health Services Authority Ex p. Martin* [1995] 1 WLR 110, [1995] 1 All ER 356 (Court of Appeal).

first one thinks that giving patients access to their own health information would diminish the value of medical records, as in the traditional practice, health practitioners adopt a candid approach to record their observations in detail, knowing that only peers, not patients, will see their medical notes.¹¹⁴³ Physicians may become uneasy when some hospitals take initiatives to let patients see doctors' notes in their systems of electronic health records (EHR).¹¹⁴⁴ Another school takes a view that informed consent will not be possible unless patients have access to information about the proposed treatments or procedures and their very own medical records including those stored in EHRs.¹¹⁴⁵ In the case of EHRs, following more common use of electronic medical records to enhance accessibility and share health information by authorized parties,¹¹⁴⁶ the ownership of electronic medical records becomes further unclear. Hall and Schulman commented that although the Recovery and Reinvestment Act 2009 in the US has reserved a budget of US\$20 billion for the implementation of clinical information systems for every American by 2014, it fails to answer the question about who owns the electronic medical information.¹¹⁴⁷

There is no universal definition of EHR.¹¹⁴⁸ Garets and Davis argued that electronic health records and electronic medical records are two completely different but important concepts for the achievement of better patient safety, improvement in healthcare quality, as well as reduction of healthcare costs.¹¹⁴⁹ In the US, the Institute of Medicine has identified that an EHR includes basic capabilities comprising longitudinal collection of electronic health information, immediate electronic access to health information on personal and societal levels, provision of knowledge and decision-support to enhance service quality and patient safety, and facilitating efficient delivery of health services.¹¹⁵⁰ The Health Information Technology for

¹¹⁴³ Baker and Masys (n 1046) 69.

¹¹⁴⁴ Rochelle Brooks and Courtney Grotz, 'Implementation Of Electronic Medical Records: How Healthcare Providers Are Managing The Challenges Of Going Digital' (2010) 8(6) *Journal of Business & Economics Research* 73, 79.

¹¹⁴⁵ Kluge (n 1080) e3.

¹¹⁴⁶ Randolph C Barrows and Paul D Clayton, 'Privacy, Confidentiality and Electronic Medical Records' (1996) 3(2) *Journal of the American Medical Informatics Association* 139, 139.

¹¹⁴⁷ Mark A Hall and Kevin A Schulman, 'Ownership of Medical Information' (2009) 301(12) *Journal of the American Medical Association* 1282, 1282.

¹¹⁴⁸ Ashish K Jha, Timothy G Ferris, Karen Donelan, Catherine DesRoches, Alexandra Shields, Sara Rosenbaum and David Blumenthal, 'How Common Are Electronic Health Records In The United States? A Summary Of The Evidence' (2006) 25(6) *Health Affairs* 496, 497.

¹¹⁴⁹ Dave Garets and Mike Davis, *Electronic Medical Records vs. Electronic Health Records: Yes, There Is a Difference* (HIMSS Analytics, Chicago, United States 2006).

¹¹⁵⁰ The Institute of Medicine of the United States, *Key Capabilities of an Electronic Health Record System: Letter Report* (July 2003) 1 <<http://www.nap.edu/catalog/10781.html>> accessed 24 May 2012.

Economic and Clinical Health Act¹¹⁵¹ has accordingly inserted a new section to the Public Health Service Act¹¹⁵² to define the term ‘certified EHR technology’, which statutorily means a qualified EHR that is properly certified in accordance with the standards set out in section 3004 of the Public Health Service Act. The US Congress also enacted the Recovery and Reinvestment Act in 2009 to require health providers to make ‘meaningful use’ of EHR technology, including electronic prescribing, information exchange, and reporting of quality measures, if they would like to achieve financial incentives.¹¹⁵³

EHRs are the key to the implementation of telemedicine.¹¹⁵⁴ The use of EHRs has been expanding worldwide because of the advantages brought about by their functionalities in collecting and using electronic health data in a systematic manner to help health practitioners’ diagnoses and treatments and facilitate patients to make informed decisions on health plans.¹¹⁵⁵ EHRs also lead to other resultant benefits such as reduced medical errors,¹¹⁵⁶ improved quality of care, lowered costs, minimized duplication of tests and treatments, better access to healthcare information in a paperless environment, as well as expanded access to affordable care, etc.¹¹⁵⁷ The Supreme Court of Oklahoma in *Johnson v Hillcrest Health Centre* noted, ‘... We recognize that medical literature reflects and supports the advent of electronic medical records and even advocates the movement towards the elimination of handwritten clinical data in the foreseeable future.’¹¹⁵⁸ To go paperless is a global trend in healthcare settings. Various programmes have been set up in developed countries and developing nations. The use of an electronic employment system¹¹⁵⁹ and an

¹¹⁵¹ United States, Health Information Technology for Economic and Clinical Health Act, section 13101.

¹¹⁵² United States, Public Health Service Act, section 3000(1).

¹¹⁵³ Phyllis Torda, Esther S Han and Sarah Hudson Scholle, ‘Easing The Adoption And Use Of Electronic Health Records In Small Practices’ (2010) 29(4) Health Affairs 668, 668.

¹¹⁵⁴ Kluge (n 1080) e2.

¹¹⁵⁵ Hodge, Gostin and Jacobson (n 572) 1466.

¹¹⁵⁶ Pauline Gearing, Christine M Olney, Kim Davis, Diego Lozano, Laura B Smith and Bruce Friedman, ‘Enhancing Patient Safety through Electronic Medical Record Documentation of Vital Signs’ (2006) 20(4) Journal of Healthcare Information Management 40.

¹¹⁵⁷ United States, Department of Health and Human Services, ‘Health Information Technology Initiative Major Accomplishments: 2004-2006’, 2

<http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848134_0_0_18/Accomplishments2006.pdf> accessed 24 May 2012.

¹¹⁵⁸ 70 P.3d 811, 2003 OK 16 (Okla., 2003) (the Supreme Court of Oklahoma), Footnote 20 (Kauger J).

¹¹⁵⁹ Tracy Hampton, ‘Hospitals and Clinics Go Green for Health of Patients and Environment’ (2007) 298(14) Journal of the American Medical Association 1625, 1626.

automated clinical record system¹¹⁶⁰ to create a filmless and paperless environment in health institutes are two examples. In the US, surveys revealed that as of 2005, only about one quarter of American doctors used EHRs.¹¹⁶¹ In 2009, the US Congress passed the Health Information Technology for Economic and Clinical Health Act to extend the availability of EHRs from large health institutes to smaller clinics and practices. It also allocated unprecedented incentive payments of up to US\$27 billion over 10 years through Medicare and Medicaid to encourage doctors and hospitals to use EHRs to improve specified health care.¹¹⁶² In the UK, it is estimated that a universally accessible EHR throughout the NHS will be available in 2014/15.¹¹⁶³ In Singapore, the use of a wireless system to share EHR information rocketed in a few years' time. Following the installation of such infrastructure in the first Singaporean public hospital in 2003, all public hospitals were able to make use of their wireless systems in 2008 to share healthcare information, to facilitate the seamless integration of financial, clinical, administrative and diagnostic processes into patient care, and even to track movement of patients, staff and physicians. The private health providers in Singapore follow suit in a similar development.¹¹⁶⁴ Cross-country cooperation in the development of EHRs is also emerging. The EC and the US signed a memorandum of understanding in late 2010 to stress the need for a joint vision on internationally recognized and utilized interoperability standards for EHRs and to promote a common approach on education programmes for IT and health professionals.¹¹⁶⁵ Use of EHRs is not confined to developed countries. The WHO launched the Health Metrics Network in 2005 to help low and low-middle income countries to enhance global health by the use of EHRs that generate healthcare information for evidence-based decision making, with a plan to develop universally

¹¹⁶⁰ Jack A Newman and Robert M Walters, 'Finally . . . Getting Value from IT Investments and Going Paperless' (2000) 1(Session 30) Proceedings of the Healthcare Information and Management Systems Society 172, 176.

¹¹⁶¹ Jha and others (n 1148) 504.

¹¹⁶² David Blumenthal and Marilyn Tavenner, 'The "Meaningful Use" Regulation for Electronic Health Records' (2010) 363(6) The New England Journal of Medicine 501.

¹¹⁶³ United Kingdom, House of Commons Public Accounts Committee, *The National Programme for IT in the NHS: Progress since 2006* (Second Report of Session 2008–09, Volume 1) (The Stationery Office, London, United Kingdom 2009) 9.

¹¹⁶⁴ Healthcare Information and Management Systems Society, HIMSS Enterprise Systems Steering Committee and the Global Enterprise Task Force, *Electronic Health Records: A Global Perspective* (2008) 96.

¹¹⁶⁵ Europe's Information Society, 'Digital Agenda: Commission signs eHealth agreement with US Department of Health' <http://ec.europa.eu/information_society/activities/health/policy/eu_usa_mou/index_en.htm> accessed 13 May 2012.

accepted standards by 2011 to govern the collection, reporting and use of health information by all developing countries.¹¹⁶⁶ In Sri Lanka, the government initiated the use of EHRs with joint collaboration with other institutes. Pilot studies have been completed and it is ready for a wider diffusion of the electronic applications in more hospitals.¹¹⁶⁷ In China, studies showed that as at 2008, 80% of hospitals were equipped with EHRs.¹¹⁶⁸

People's perception towards EHRs is diverse. Whilst EHRs provide benefits to health services, privacy concerns are deepened by the fear of unauthorized access to health information, as well as misuse, modification or erasure of personal medical data by people who are authorized to get access to it.¹¹⁶⁹ Westin's survey found that Americans had divided views when they answered the question on whether they felt the expected benefits of EHRs would outweigh potential risks to privacy. 48% of the respondents said the benefits outweighed risks to privacy and 47% answered the other way round.¹¹⁷⁰

Also, new medico-legal implications arise. On the positive side, EHRs give health practitioners a certain degree of protection from claims of clinical negligence, as electronic patient records are more legible, standardized documentation is available, laboratory results are automatically notifiable, and communications between health practitioners are comparatively more efficient.¹¹⁷¹ The other side of the coin shows that new legal challenges arise from EHRs. For instance, EHRs will introduce new types of adverse medical events like health practitioners' making errors when selecting from pull-down menus of the systems.¹¹⁷² The availability of electronic health information also results in privacy risks,¹¹⁷³ especially when proprietary network systems are gradually replaced by new applications involving a series of multiple

¹¹⁶⁶ World Health Organization, Health Metrics Network, *Framework and Standards for Country Health Information Systems* (2nd edn, WHO Press, Geneva, Switzerland, 2008).

¹¹⁶⁷ Clarice Africa, 'Sri Lankan Hospitals to go paperless' *FutureGov* (Singapore, 4 January 2012) <<http://www.futuregov.asia/articles/2012/jan/04/sri-lankan-hospitals-go-paperless/#>> accessed 27 May 2012.

¹¹⁶⁸ Liang and others (n 206) 281.

¹¹⁶⁹ Datta and Dunlop (n 987) 6-8 §6.01[3].

¹¹⁷⁰ Alan F Westin, 'Public Attitudes Toward Electronic Health Records' (2005) 12(2) *Privacy & American Business* 1, 4.

¹¹⁷¹ Michael Vigoda, Jill Callahan Dennis and Michelle Dougherty, 'e-Records, e-Liability: Addressing medico-legal issues in electronic records' (2008) 79(10) *Journal of American Health Information Management Association* 48, 49.

¹¹⁷² Dean-Franklin, as cited in United Kingdom, House of Commons Health Committee, *Patient Safety* (Sixth Report of Session 2008–09, Volume 1) (The Stationery Office, London, United Kingdom 2009) 57 [156].

¹¹⁷³ Landgreen (n 142) 387.

servers¹¹⁷⁴ – inside by intranets and/or outside by the Internet-based EHRs¹¹⁷⁵ accessible to patients via their computers. Health practitioners and institutes should not overlook the potential risks of breach of patient data privacy, as it has been reported that computerized healthcare databases may be intruded more easily than paper-based records.¹¹⁷⁶ In Taiwan, owing to the concerns about patient data privacy and security, many hospitals were hesitant to participate in a large scale sharing of electronic patient information.¹¹⁷⁷

Health practitioners and institutes should not underestimate other legal challenges due to EHRs, either, which include but are not limited to changing standards of practice, documentation issues, and e-discovery.¹¹⁷⁸ In considering the standard of care, the wide-spread use of EHRs may change the way in which courts determine the standard of care and therefore may reshape medical liability by changing the standard of care itself, as the court may accept clinical-decision support protocols embedded in an EHR as a more accurate definition of the standard of care than the personal standard described by experts alone. Health practitioners shouldering the burden of proof have to convince the court and juries in cases where they deliberately override the EHR guidelines and protocols that such overriding still constitutes a reasonable standard of care and is therefore not a breach of duty of care.¹¹⁷⁹

Documentation poses additional medico-legal risks that if inconsistent documentation practices are to be used in the same EHR by different health practitioners, key patient information input by one practitioner may not catch the eye of others who are used to inputting the same diagnosis in different manners.¹¹⁸⁰ In the US, the Interagency Committee on Medical Records approved a set of guidelines for adoption throughout the federal health care system to document telemedicine,¹¹⁸¹

¹¹⁷⁴ Francis Roger-France, 'Security of Electronic Health Care Records: A Clinical Perspective' in the ISHTAR Consortium (ed), *Implementing Secure Healthcare Telematics Applications in Europe* (IOS Press, Amsterdam, the Netherlands 2001) 23.

¹¹⁷⁵ Benigeri and Pluye (n 1107) 382.

¹¹⁷⁶ Hodge, Gostin and Jacobson (n 572) 1467.

¹¹⁷⁷ Science & Technology Advisory Group of Taiwan (2006), as cited in In Chang, 'Stakeholder Perspectives on Electronic Health Record Adoption in Taiwan' (2010) 15(1) *Management Review* 133, 142.

¹¹⁷⁸ Vigoda, Dennis and Dougherty (n 1171) 48.

¹¹⁷⁹ Sandeep S Mangalmurti, Lindsey Murtagh and Michelle M Mello, 'Medical Malpractice Liability in the Age of Electronic Health Records' (2010) 363(21) *New England Journal of Medicine* 2060.

¹¹⁸⁰ Vigoda, Dennis and Dougherty (n 1171) 52.

¹¹⁸¹ United States, 'Interagency Committee for Medical Records (ICMR); Documentation of Telemedicine' (1996) 61(237) *Federal Register* (Billing Code 6820-34-M) 64908.

including patients' written consent before videotaping an encounter, written documentation of a telemedical consultation by health practitioners on both ends of the encounter, and erasure of any permanent video images after completion of written documentation (except in cases with exceptional educational value). As far as medico-legal liability is concerned, it is not clear whether a videotape of a procedure or consultation may become part of a patient's medical record, but if videotapes are available for some patients but not for all, absence of a videotape may create a perception of purposeful destruction of evidence.¹¹⁸²

EHRs also facilitate electronic discovery or 'e-discovery'. Clinical negligence litigation will inevitably involve requests for medical records. If such records are stored in EHRs, health institutes have to take initiatives to develop a protocol for possible e-discovery to manage the complex record gathering process, to facilitate lawyers to review large volumes of medical information, and to make it available at the organizational 'fingertips' so as to demonstrate to the court good faith information management services.¹¹⁸³ The success of this e-discovery process depends on the collaboration of a team of specialists such as lawyers, IT professionals and health information record managers. This team needs to identify where the records are stored for a given period of time, for example, the backup data, emails storing the medical information, the possibility of retrieval of deleted data, and whether there is a need to restore data format from, say, PDF format to MSWord format, etc.¹¹⁸⁴ Through e-discovery, lawyers may identify more abundant information stored in the electronic patient database than in paper records.¹¹⁸⁵ In fact, the US has revised its Federal Rules of Civil Procedure since 2006 to address issues of e-discovery and to ask lawyers to pay special attention to this new area in the process of discovery. Its Rule 26, for instance, governs the disclosure of electronically stored information and Rule 45 specifies the ways a subpoena should seek digital information. Subsequent to e-discovery, telemedicine health practitioners may also be required to produce patient medical records and other materials and appear physically in the jurisdictions where concerned patients locate. For example, the Oregon Medical Board in the US is empowered to ask an 'across state line' physician to

¹¹⁸² Ibid.

¹¹⁸³ Sandra Nunn, 'Applying Legal Holds to Electronic Records' (2008) 79(10) *Journal of American Health Information Management Association* 72, 73.

¹¹⁸⁴ Ibid.

¹¹⁸⁵ Scott A Carlson and Ronald L Lipinski, 'eDiscovery: A New Approach to Discovery in Federal and State Courts' (2007) 95(4) *Illinois Bar Journal* 184.

produce medical records and appear before the Board,¹¹⁸⁶ failing which is subject to disciplinary action in accordance with the Medical Practice Act.¹¹⁸⁷

6.2.2.2.3.1 Protection of Electronic Patient Data

The use of EHRs challenges traditional patient data protection in three aspects: individual patients' identifiable health information, data quality and reliability, as well as tortious liability.¹¹⁸⁸ How to protect electronic patient information against intrusion is 'one of the most challenges of the information age.'¹¹⁸⁹ Requests for protection of patient data and information stored and/or transmitted electronically have become more frequent in recent years. In telemedicine, both real-time consultations and 'store-and-forward' transmissions may involve electronic medical records. After completion of a telemedical service, there are risks that among others, unauthorized people may send such patient information which is left carelessly on a telemedicine workstation to any corner of the world or make use of the information improperly.¹¹⁹⁰ Hodge and colleagues have suggested that better protection of patient data privacy with some control mechanisms reduce tort-based liability, as the control mechanisms help minimize the risk of clinical negligence, safeguard data from invasion of individual privacy, enhance data quality and reliability, as well as improve clinical care.¹¹⁹¹ The next question then is how to strike a balance between patient data protection and other health activities such as medical research for the public good. In the UK, when the Data Protection Act 1998 (UK) came into effect, some health practitioners and the NHS trusts refused to continue the supply of health data to other health institutes for the fear of possible breach of confidentiality without patients' consent and breach of the statutory requirements. The situation was improved only after the Information Commission issued guidance to clarify the misconceptions arising from the Act.¹¹⁹² In *R v*

¹¹⁸⁶ Oregon Medical Board, *Oregon Administrative Rules – Division 025, Rules for Licensure to Practice Medicine Across State Lines*, OAR 847-025-0060(2).

¹¹⁸⁷ §677.190.

¹¹⁸⁸ Hodge, Gostin and Jacobson (n 572) 1467.

¹¹⁸⁹ Sanders and Bashshur (1995) (n 32) 120.

¹¹⁹⁰ Glenn Wachter, 'HIPAA's Privacy Rule Summarized: What Does It Mean For Telemedicine?' *Telemedicine Regulatory Issue Summary* (26 February 2001) 6

<http://mdconsult.net/news/newsresources/hipaa2001_2.pdf> accessed 1 June 2012.

¹¹⁹¹ Hodge, Gostin and Jacobson (n 572) 1467.

¹¹⁹² P Boyd, 'The requirements of the Data Protection Act 1998 for the processing of medical data' (2003) 29(1) *Journal of Medical Ethics* 34, 34.

Department of Health Ex p. Source Informatics Ltd (No.1),¹¹⁹³ the appellant appealed against a declaration that pharmacists' release of anonymous prescription information to pharmaceutical companies for commercial medical research constituted a breach of confidence. The Court of Appeal overturned the trial court's decision and held that use of anonymized patient data does not breach confidentiality and patients had no property rights to the prescription or the information contained therein as all personal details had been expunged. In response to this ruling, a professor of medicine said, 'it will now be possible, subject to getting ethical approval, to carry out important ... research ... which are an integral part to monitoring drug safety in man.'¹¹⁹⁴

Legal protection has been provided in some jurisdictions. Various measures have been adopted to safeguard the custody of medical records and protect patients' access to these records. In Singapore, electronic records are protected under the Computer Misuse Act¹¹⁹⁵ against computer crime and the Electronic Transactions Act for effective electronic communications through reliable electronic records and promotion of public confidence in the integrity and reliability of electronic records and electronic commerce.¹¹⁹⁶ The Private Hospitals and Medical Clinics Act also requires licensed health institutes to keep and maintain proper records for every patient.¹¹⁹⁷ In the UK, the Access to Health Records Act 1990 (UK) empowers the court to order the holder of a health record which has failed to comply with any statutory requirements therein to comply with that requirement.¹¹⁹⁸ Also, its Pre-action Protocol for the Resolution of Clinical Disputes outlines the steps for claimants in clinical cases to obtain medical records from hospitals and third parties.¹¹⁹⁹ In the US, the Health Insurance Portability and Accountability Act 1996 requires the Department of Health and Human Services to issue the Standards for Privacy of Individually Identifiable Health Information to cover all electronic and non-electronic 'protected health information'.¹²⁰⁰ In China, though it is not specifically for protection of electronic patient data, the Chinese HMA Regulation 2002 stipulates that in any medical disputes, the health institute concerned has to keep medical records such as

¹¹⁹³ [2001] QB 424, [2000] 1 All ER 786 (Court of Appeal).

¹¹⁹⁴ As cited in Tessa Richards, 'Court sanctions use of anonymised patient data' (2000) 320(7227) British Medical Journal 77, 77.

¹¹⁹⁵ Chapter 50A

¹¹⁹⁶ Chapter 88, section 3.

¹¹⁹⁷ Cap 248, section 17.

¹¹⁹⁸ Section 8(1).

¹¹⁹⁹ [3.7]-[3.13].

¹²⁰⁰ 45 CFR §160.103.

clinical diagnosis, records of specialist consultations and ward-round notes, etc. These materials to be kept may be photocopies and have to be sealed and opened in the presence of both parties to the dispute.¹²⁰¹

Despite the efforts of different jurisdictions, patient data protection still lags behind IT development, as law being a means of reflecting political opinion will take more time to develop than the technical development of the Internet.¹²⁰² In theory, liability concerns should drive the hardware and software of telemedical applications to gear up with the newest and best technologies, but in practice, it is common that systems used in telemedicine become outmoded quickly and cannot catch up with technological advancement.¹²⁰³ In the US, there are criticisms on the inadequate protection of health informational privacy by its federal and state privacy laws.¹²⁰⁴ Following the enactment of the Health Insurance Portability and Accountability Act in 1996, it was expected that greater protection would be provided for electronic transmissions of health information.¹²⁰⁵ However, after the Act has been running for over a decade, the Institute of Medicine of the US has recently concluded that while it does not provide adequate protection of patient data privacy, it essentially impedes high-quality research.¹²⁰⁶

Another concern is the lack of up-to-date privacy policy in health institutes. There are a few principles useful for the protection of patient privacy and the confidentiality of health information, for example, physical security of storage and archival, security of storage media, and especially for electronic data, right of access and audit trails.¹²⁰⁷ In actual practice, although security measures such as encryption, passwords and legal restrictions may help reduce the risk of intrusion to IT systems and facilitate better patient data protection, no system can offer a 100% guarantee. The question is what constitutes a reasonable and sufficient standard of protection.¹²⁰⁸ Many scholars have pointed out that the major problem inherent in the healthcare

¹²⁰¹ Art 16.

¹²⁰² Allaert and Barber (n 1081) 101.

¹²⁰³ Kluge (n 1080) e3.

¹²⁰⁴ Hodge, Gostin and Jacobson (n 572) 1468.

¹²⁰⁵ United States, Health Insurance Portability and Accountability Act, section 261.

¹²⁰⁶ The Institute of Medicine of the United States, *Report Brief – Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research* (February 2009) 1
<http://www.iom.edu/~media/Files/Report%20Files/2009/Beyond-the-HIPAA-Privacy-Rule-Enhancing-Privacy-Improving-Health-Through-Research/HIPAA%20report%20brief%20FINAL.pdf>
 accessed 27 May 2012.

¹²⁰⁷ Quan, 'Medical Records and Confidentiality' (n 1129) 217 [6.14].

¹²⁰⁸ Sanders and Bashshur (1995) (n 32) 120.

system is its lack of a cohesive security policy,¹²⁰⁹ owing to the ever-changing legal concept of privacy to reflect the private and public interests of society.¹²¹⁰ In cross-border telemedicine practice, it is essential that a privacy policy should be planned in advance. For example, Ruotsalainen has proposed the enhancement of privacy and security measures in teleradiology, including adoption of a common security policy governing all parties involved, a common set of security and privacy protection principles and requirements, and controlled contracts among parties, together with the use of security controls and tools, as well as certification of the whole teleradiology service system including security and privacy.¹²¹¹

On top of the institutional lack of security and privacy policy, a further issue is people's awareness of privacy risks. Although there are statutory protection provisions, a US survey in 1997 revealed that health law experts were not greatly concerned about privacy issues.¹²¹² In Hong Kong, there has been a recurrence of incidents in violation of the duty of confidentiality. In 2009, a doctor in Hong Kong lost a Universal Serial Bus, or commonly known as a USB, containing 47 eye patients' demographic and medical data.¹²¹³ In 2012, another young doctor uploaded information concerning a psychiatric patient onto the Facebook.¹²¹⁴

To go paperless needs careful planning in advance, as a safe and good system design helps minimize the liability of health practitioners and institutes. Nemeth and Cook commented that new telematic systems without a deep understanding of how health care works are only experiments to guess how such systems should be designed,¹²¹⁵ and systems so developed are vulnerable to failure. Kluge also said that allowing technology to determine how health care should be delivered may result in serious ethical and legal problems.¹²¹⁶ It has been recognized that new telematic systems are no longer solutions to well defined problems but are

¹²⁰⁹ Barrows and Clayton (n 1146) 140.

¹²¹⁰ Ibid 141-142.

¹²¹¹ Pekka Ruotsalainen, 'Privacy and security in teleradiology' (2010) 73(1) *European Journal of Radiology* 31.

¹²¹² Susan M Webster, 'Consolidation Remains Top Legal Issue For Health Care Industry in New Year' (1997) 6 *Health Law Reporter (BNA)* 5, as cited in Caryl (n 130) 182.

¹²¹³ 'A doctor lost a USB involving 47 eye patients' (醫生再失 USB 手指涉 47 眼科病人'; *yī shēng zài shī USB shǒu zhǐ shè 47 yǎn kē bìng rén*) *Sing Tao Daily* (Hong Kong, 24 March 2009).

¹²¹⁴ 'Doctor is criticized for his unauthorized posting of medical records onto the Facebook' (擅將病历上載 fb 醫生捱轟'; *shàn jiàng bìng lì shàng zài fb yī shēng ái hōng*) *Sing Tao Daily* (Hong Kong, 8 March 2012).

¹²¹⁵ Christopher Nemeth and Richard Cook, 'Hiding in plain sight: What Koppel et al. tell us about healthcare IT' (2005) 38(4) *Journal of Biomedical Informatics* 262, 263.

¹²¹⁶ Kluge (n 1080) e2.

information systems only to serve two purposes: being the infrastructure to share a database through the collection and processing of personal data and for meeting future purposes.¹²¹⁷ A number of factors have to be taken into account in the system design, for instance, health practitioners' attitudes toward telemedicine,¹²¹⁸ criteria of assessing a telematic system involving necessity, transparency, quality, as well as security and confidentiality,¹²¹⁹ use of an open architecture to maximize the system potential for future enhancement, user requirements, operational efficiency, maintenance cost, and compatibility with other systems in the same country and worldwide,¹²²⁰ etc. Japan shows an example of how a lack of planning may affect the end results. In Japan, the Basic Act on Establishing a Networked Society Based on Advanced Information and Telecommunications requires the use of a broadband system to facilitate monitoring of patients in ambulances.¹²²¹ However, the Japanese government leaves the development of telecommunication infrastructure to the private sector, leading to failure in transmitting a large volume of data from ambulances to distant health practitioners and thus violating the above Act.¹²²² Both the legislative introduction of the Act and the control of telecommunication infrastructure were on the hands of the Japanese government. It is arguable if it had planned and designed the whole system in a robust manner, the teleambulance service would have achieved a better result than that reported above. Before using EHRs, health institutes or practitioners are advised to discuss with their medical liability insurers to check any implications for insurance premiums, seek the support of health information professionals to ensure that their planned electronic systems meet their legal and operational needs, and ask vendors to address any medico-legal concerns.¹²²³

6.2.3 Patient Liability

The right to health and the right to access to healthcare services have been internationally recognized as basic individual rights. At the international level, two components constitute the right to health: freedom and entitlements. The term

¹²¹⁷ Jean Herveg and Yves Poulet, 'Which Major Legal Concerns in Future e-Health' (2007) 233 IFIP International Federation for Information Processing 159, 161.

¹²¹⁸ Liu Sheng and others (n 41) 272.

¹²¹⁹ Herveg and Poulet (n 1217) 161-167.

¹²²⁰ Sanders and Bashshur (1995) (n 32) 121-122.

¹²²¹ Art 21.

¹²²² Juzoji (n 156) 42.

¹²²³ Vigoda, Dennis and Dougherty (n 1171) 51.

‘freedom’ refers to the control of one’s health and body, examples of which include the rights to be free from interference by others and free from torture. ‘Entitlements’ means people’s right to have an ‘equality of opportunity for [them] to enjoy the highest attainable level of health’,¹²²⁴ and allow people to get access to health facilities, goods and services without discrimination.¹²²⁵ How to legally protect patients’ rights at the national level varies from country to country.¹²²⁶ In the context of telemedicine, the patients’ right to freely choose a health practitioner¹²²⁷ and the right to be reimbursed for healthcare expenses abroad are the most relevant ones. In the EU, the European Court of Justice has consistently affirmed patients’ right to have reimbursement for health care received abroad that they would have received at home.¹²²⁸

Patient liability and patient rights are two sides of the same coin. Generally speaking, there is no specific liability attached to patients in the legal health practitioner-patient relationship.¹²²⁹ In the US, the term ‘patient liability’ is in general referring to the insurance amount a consumer has to contribute for long-term care services like Medicaid.¹²³⁰ In fact, the scope of patient liability is more than this insurance component. In a legal sense, there is always a misperception that patients only play a passive role to ensure that a health practitioner’s care is up to standard.¹²³¹ A barrister in Pennsylvania in the US said, ‘One issue ... is to what extent patients contribute to their own health problems but then blame their doctors ... Despite the non-compliance [of medical advice], when something goes wrong ... it is the physician’s fault!’¹²³² In Canada, the Court of Appeal (Newfoundland) in *Brushett v Cowan*¹²³³ held that although the patient consent form was not clear to allow the

¹²²⁴ United Nations Committee on Economic, Social and Cultural Rights of the Economic and Social Council (n 112) [8].

¹²²⁵ Ibid [12(b)].

¹²²⁶ European Commission, Directorate General Information Society (2009) (n 163) 66.

¹²²⁷ Ibid 67.

¹²²⁸ European Commission, *Communication from the Commission: A Community framework on the application of patients’ rights in cross-border healthcare* (European Commission, Brussels, 2008, SEC(2008) 2183, COM(2008) 415 final) 2.

¹²²⁹ Rienhoff and others (eds) (n 188) 91.

¹²³⁰ See, for example, United States, North Carolina, Office of Administrative Hearings, North Carolina Administrative Code 10a NCAC 21B .0407; United States, Ohio, Department of Job and Family Services, *Understanding Patient Liability – A monthly payment for long-term care services*, 2 <<http://www.odjfs.state.oh.us/forms/file.asp?id=1677&type=application/pdf>> accessed 24 April 2012.

¹²³¹ Yeo Khee Quan, ‘Medico-Legal Reform’ in Quan and others (n 324) 341 [10.64].

¹²³² James W Saxton, ‘Reducing liability through patient accountability’ *Physician’s News Digest* (May 2003) <<http://www.physiciansnews.com/law/503saxton.html>> accessed 22 May 2012.

¹²³³ [1991] 2 Med LR 271 (Court of Appeal (Newfoundland)).

defendant doctor to carry out a biopsy, the patient claimant's failure to ask amounted to contributory negligence and she had to bear 20% of the damages.

Actually, patients can take a more active role when patient liability is viewed from the perspective of patient empowerment. Empowering patients to play an active role in the provision of their own care is beneficial to both patients and health practitioners, as this empowerment acknowledges their shared responsibility in the delivery of health care.¹²³⁴ Patients not only have the right to make medical decisions but also the responsibility to face the results of going along with those decisions.¹²³⁵ While they can request health information to facilitate their making of informed decisions, they have the responsibility to learn sufficiently about their illnesses to ask the correct questions.¹²³⁶ It is also their responsibility to provide health data to health practitioners.¹²³⁷ Patients' knowledge of their medical conditions and assumption of personal responsibility will enhance their health to a great extent and determine the outcome of disease management.¹²³⁸ In practice, a 5-star private hospital in Hong Kong has presented a list of patients' responsibility on its website as follows: patients' candour about their illness and medical history, compliance with agreed treatment plans, not requesting untrue documentation like false sick leave certificates, timely payment settlement, following hospital rules, paying respect to hospital staff and other patients, proactively asking for adequate explanations for any treatments they do not understand, and timely reporting of any change in their medical conditions.¹²³⁹

'True implementation of telemedicine ... involves training patients to communicate through technologies.'¹²⁴⁰ Telemedicine empowers patients through self-service tools such as online health education and access to health information, and when patients are empowered, they become informed participants to take their own medical decisions and share accountability between health practitioners and

¹²³⁴ Baker and Masys (n 1046) 67.

¹²³⁵ Quan, 'Medico-Legal Reform' (n 1231) 342 [10.67].

¹²³⁶ Ibid.

¹²³⁷ Rienhoff and others (eds) (n 188) 105.

¹²³⁸ Ronald C Merrell, 'The Medical Traveler Abroad: Implications for Telemedicine' in Nelson and Ball (eds) (2004) (n 1046) 146.

¹²³⁹ Hong Kong Sanatorium & Hospital, 'Patients' Rights and Responsibilities' <<http://www.hksh.com/en/patients/patientprivacy.html>> accessed 20 June 2012.

¹²⁴⁰ Richard L Nevins and Ronald J Pion, 'Telemedicine Becomes a Reality with Web-Enabled Applications and Net Devices' in Douglas E Goldstein (ed), *e-Health: Harness the Power of Internet e-Commerce & e-Care* (Aspen Publication, Maryland, United States 2000) 198.

themselves.¹²⁴¹ The World Medical Association¹²⁴² has promulgated that in some situations, patients should assume responsibility for the collection and transmission of data to health practitioners. Health practitioners have to train their tele-patients in the necessary procedures and ensure that they are physically capable and understand the importance of their roles in telemedicine. The same principle is also applicable to relatives or caretakers of the patients.

New medico-legal concerns emerge from patient empowerment in telemedicine. In the case of home tele-monitoring, for instance, if medical errors are made owing to mistakes in taking readings or misreporting data or accidental interference with the telemedical device by patients or their family members, it raises the issue of apportioning legal liability.¹²⁴³ Another issue is whether the traditional paternalistic health practitioner-patient relationship would still be applicable in this patient-empowered relationship with co-sharing of responsibility for disease management.¹²⁴⁴

6.3 Chapter Conclusion

In this chapter, patients' concerns in the practice of telemedicine are discussed. Patient safety is a real concern as revealed by the WHO, Europe, the UK and the US. Telemedicine helps improve patient safety through technologies such as remote continuous patient monitoring to enhance compliance with treatment plans and sharing of patient data instantaneously, but it also creates new risks, e.g. telemedical equipment failure and missing patient data during electronic transmission. Informed consent is a means through which health practitioners may clearly explain the inherent risks of telemedicine to patients in addition to traditional explanations of risks and benefits of treatment options or having no treatment. New issues will arise when patients sign their consent online if the legal position of electronic signatures is not clear. Following international input from the EU and the UN such as the promulgation of directives and issuance of UNCITRAL model laws, more and more jurisdictions have enacted their own domestic legislation to govern electronic

¹²⁴¹ Ibid 201.

¹²⁴² World Medical Association, World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine (n 735) §16.

¹²⁴³ Kluge (n 1080) e3.

¹²⁴⁴ Ibid.

transactions, though the efficacy of these statutes is still subject to further case law tests as observed by Forder.¹²⁴⁵

Patient data protection is another significant and important patient concern, especially when people worry about their privacy and fear the misuse or malicious use of their health information. Telemedicine adds new risks to patients' privacy right, as the Internet is fundamentally an open communication system susceptible to attacks. New issues such as unauthorized user access, problems of authenticity, illegal interception during data transmission, data integrity, changing technical standards, data documentation, and e-discovery etc. arise when health practitioners use emails or health-related websites to make communication with patients or make use of EHRs to facilitate management of medical records and telemedical practices. These issues may affect the admissibility of electronic information in court. Professional entities and governments have tried their efforts through professional codes of practice and legislation to safeguard electronic patient data.

Patient liability was not accorded a high priority. People recognize now the importance of patient empowerment which is beneficial to health practitioners and patients through a shared responsibility of disease management. Telemedicine facilitates this responsibility sharing through applications such as home tele-monitoring whereby patients and their supporters input medical conditions to telemedical devices and health practitioners monitor patients' conditions in another corner of the world. However, this is again a double-edge sword. Apportionment of legal liability may be a concern when clinical negligence claims arise from, for example, misunderstanding of treatment procedures, mistaking of health data or misreporting on the side of patients and supporters.

¹²⁴⁵ Forder (n 948) 426.

CHAPTER 7

Other Areas of the SIREN Liability Framework (2):

Institutional Concerns and Criminal Liability

‘Each of us individually, and the medical profession as a collective, must find a mechanism with which to deal with the impact of [exponential] change on our lives, on their patients, and on our relationships.’

— Jack R London¹²⁴⁶

7.1 Chapter Summary

The medical liability of health practitioners and areas of concerns from the patients’ angle have been studied in the previous chapters. In this chapter, discussion on the remaining SIREN elements from the institutional aspect, namely organizational liability, service liability, product liability and contractual liability, continues. By the term ‘institutional’, it does not necessarily mean that all liabilities rest on institutes like hospitals, health management organizations or clinics. Health practitioners have also had an institutional role to play when, for instance, they employ others to work for them or install telemedicine systems through the assistance of equipment vendors or making use of websites and/or emails to provide telemedical services for patients. The criminal liability related to telemedicine will be addressed at the penultimate section of this chapter.

7.2 Liability from the Perspective of Health Institutes

Health institutes have four general duties as summarized by the Supreme Court of Pennsylvania in *Thompson v Nason Hospital* in the US. They have a duty to select and retain only competent staff, a duty to oversee and monitor the clinical services practised by those within their walls, a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients, and a duty to use reasonable care to maintain safe and adequate facilities and equipment.¹²⁴⁷ These four duties are in general associated with organizational liability, service liability, product liability and contract liability.

¹²⁴⁶ Jack R London, ‘Exponential Change: Today is Already Tomorrow’ (1994) 3 *Annals of Health Law* 153, 166.

¹²⁴⁷ 527 Pa. 330, 339-340, 591 A.2d 703,707 (Pa., 1991) (Supreme Court of Pennsylvania).

7.2.1 Organizational Liability

7.2.1.1 Direct Liability

Health practitioners and institutes may face direct liability and vicarious liability.¹²⁴⁸ Direct liability for negligence can arise through corporate negligence, non-delegable duty and liability for defectively designed healthcare systems.¹²⁴⁹ Those practitioners and institutes with poor administration or an unsafe system of work may assume direct liability themselves in any adverse medical events.¹²⁵⁰ In the UK, Browne-Wilkinson VC sitting on the Court of Appeal in *Wilsher v Essex Area Health Authority* said, '[A] health authority which ... fails to provide doctors of sufficient skill and experience to give the treatment offered at the hospital may be directly liable in negligence to the patient.'¹²⁵¹ The Court of Appeal in *Robertson v Nottingham HA*¹²⁵² reaffirmed that the NHS has a non-delegable duty to provide a proper system of care for patients. In the US, organizational liability was firstly confined to hospitals and has been expanded to cover other health institutes.¹²⁵³ In *Darling v Charleston Community Memorial Hospital*,¹²⁵⁴ the Supreme Court of Illinois held for the first time that hospitals having a charitable status cannot limit their liability for torts to the amount of their liability insurance. In *Thompson v Nason Hospital*,¹²⁵⁵ the Supreme Court of Pennsylvania also noted that corporate negligence creates a non-delegable duty which the hospital owes directly to a patient. In *Jones v Chicago HMO*,¹²⁵⁶ the Supreme Court of Illinois ruled that a health maintenance organization may be held liable for corporate negligence and expert testimony is not always required to establish the standard of care applicable to the organization.

¹²⁴⁸ Barbara A Noah, 'The Managed Care Dilemma: Can Theories of Tort Liability Adapt to the Realities of Cost Containment' (1996-1997) 48(3) Mercer Law Review 1219, 1232.

¹²⁴⁹ Kuszler (n 5) 321.

¹²⁵⁰ Powell, Stewart and Jackson (eds) (2007) (n 391) 953 [13-060].

¹²⁵¹ [1987] QB 730, 778, [1986] 3 All ER 801 (Court of Appeal).

¹²⁵² [1997] 8 Med LR 1, (1997) 33 BMLR 178 (Court of Appeal).

¹²⁵³ Kuszler (n 5) 319.

¹²⁵⁴ 33 Ill. 2d 326, 211 N.E.2d 253 (Ill. 1965) (Supreme Court of Illinois).

¹²⁵⁵ 527 Pa. 330, 339, 591 A.2d 703, 707 (Pa., 1991) (Supreme Court of Pennsylvania).

¹²⁵⁶ 191 Ill.2d 278, 730 N.E.2d 1119 (Ill., 2000) (Supreme Court of Illinois).

7.2.1.2 Vicarious Liability

7.2.1.2.1 Servants

As for vicarious liability, it is important to distinguish between employees over whom employers have control in their performances and independent contractors who work for others but whose performances are not controlled by the other parties. In general, employers bear vicarious liability when their employees commit a tort, regardless of whether the employers have committed the tort themselves, but they may not be liable for any torts committed by their independent contractors.¹²⁵⁷ In the UK, in *Bartonshill Coal Co v McGuire*, Lord Chelmsford LC in the House of Lords said, '[E]very act which is done by a servant in the course of his duty is regarded as done by his master's orders, and consequently is the same as if it were his master's own act.'¹²⁵⁸ Health institutes may assume vicarious liability for any medical mishaps caused by their employee health practitioners. Lord Denning sitting on the Court of Appeal in *Roe v Minister of Health* said,

... the hospital authorities are responsible for the whole of their staff, not only for the nurses and doctors, but also for the anaesthetists and the surgeons. It does not matter whether they are permanent or temporary, resident or visiting, whole-time or part-time. The hospital authorities are responsible for all of them. The reason is because, even if they are not servants, they are the agents of the hospital to give the treatment. The only exception is the case of consultants or anaesthetists selected and employed by the patient himself.¹²⁵⁹

In the US, after the ruling of *Darling v Charleston Community Memorial Hospital*,¹²⁶⁰ health institutes pay more attention to peer review by health practitioners as an ongoing credentialing process to train their staff, as the institutes are now subject to organizational liability under which they could be held liable for a patient injury caused by a staff member if they should have known the staff member's

¹²⁵⁷ John Murphy and Christian Witting, *Street on Torts* (13th edn, Oxford University Press, Oxford 2012) 640-646.

¹²⁵⁸ (1858) 3 Macq 300, 306 (House of Lords).

¹²⁵⁹ [1954] 2 QB 66, 82, [1954] 2 All ER 131 (Court of Appeal) (Lord Denning).

¹²⁶⁰ 33 Ill. 2d 326, 211 N.E.2d 253 (Ill. 1965) (Supreme Court of Illinois).

poor performance and incompetence but failed to take reasonable actions to improve his or her performance and skills.¹²⁶¹ This credentialing requirement extends to the process of recruitment. In *Johnson v Misericordia Community Hospital*,¹²⁶² the Supreme Court of Wisconsin held that a hospital is under a duty to exercise reasonable care to permit only competent medical doctors the privilege of using their facilities.

7.2.1.2.2 Independent Contractors

Clinical negligence may not necessarily be caused only by employee health practitioners. An independent health practitioner under a contractual relationship with a health institute may also cause a medical mishap. Are health institutes vicariously liable for torts committed by independent contractors? The courts' positions are changing in common law jurisdictions. At common law, the doctrine of vicarious liability has long been controversial,¹²⁶³ and the legal position about whether the status of a health practitioner being an independent contractor should shield a hospital from any liability of his or her negligence has also undergone changes over time. In the US, Isbey said that most of the cases in the mid-twentieth century refused to find a hospital vicariously liable for the negligence of an independent-contractor doctor, as the doctrine of respondeat superior requires that the doctor be a hospital employee.¹²⁶⁴ Hamilton found that in the latter half of the twentieth century, courts in the US increasingly held hospitals liable for the negligence of independent-contractor doctors under the doctrine of apparent agency.¹²⁶⁵ Alstott pointed out the same prevalence in recent years that hospitals were found liable for the negligence of independent-contractor doctors in 27 states and the District of Columbia in the US.¹²⁶⁶ In addition to the doctrine of apparent

¹²⁶¹ Marvin H Firestone, 'Medical Staff Peer Review in the Credentialing and Privileging of Physicians' in Sanbar and others (eds) (2004) (n 988) 87.

¹²⁶² 99 Wis.2d 708, 301 N.W.2d 156 (Wis., 1981) (Supreme Court of Wisconsin).

¹²⁶³ Paula Giliker, 'Vicarious Liability or Liability for the Acts of Others in Tort: A Comparative Perspective' (2011) 2(1) *Journal of European Tort Law* 31, 31.

¹²⁶⁴ Elizabeth Isbey, '*Diggs v. Novant Health, Inc.* and the Emergence of Hospital Liability for Negligent Independent-Contractor Physicians in North Carolina' (2008) 43(4) *Wake Forest Law Review* 1127, 1131.

¹²⁶⁵ Hadley Hamilton, '*Boren Ex. rel. Borren v. Weeks* and the Extension of Apparent Agency Liability to Tennessee Hospitals for the Negligence of Independent Contractor Physicians: Does the Fine Print Really Matter Anymore?' (2010) 29(2) *Temple Journal of Science Technology and Environmental Law* 257, 266.

¹²⁶⁶ Adam Alstott, 'Hospital Liability for Negligence of Independent Contractor Physicians Under Principles of Apparent Agency' (2004) 25(4) *The Journal of Legal Medicine* 485, 490.

agency, other legal doctrines are also considered in the US courts. For example, the Supreme Court of Illinois in *Petrovich v Share Health Plan*¹²⁶⁷ held that vicarious liability may be imposed on a health maintenance organization for the negligence of its independent-contractor physicians under the doctrine of implied authority or ostensible authority. The Court of Appeal of California in *Elam v College Park Hospital*¹²⁶⁸ held that a hospital is liable to a patient under the doctrine of corporate negligence for the negligent conduct of independent doctors who are neither employees nor agents of the hospital but avail themselves of the hospital facilities.

In the UK, the court's standing in relation to vicarious liability of health institutes has also changed in the recent decades. Until the 1940s, courts were reluctant to hold hospitals vicariously liable for the negligence of an employee doctor,¹²⁶⁹ out of the concerns such as the control of a health institute over doctors who are professionals where they 'exercise their profession to the best of their abilities according to their own discretion; but in exercising it they are in no way under the orders or bound to obey the directions of the [defendant hospital].'¹²⁷⁰ Another concern of the courts was the threat to the charitable status of defendant hospitals. Lord President said in a Scottish case, *MacDonald v Glasgow Western Hospitals Board of Management*,

... most of the earlier decisions regarding voluntary hospitals (or hospitals which were assumed to be voluntary) were deeply influenced by the desire to protect charitable funds from claims for damages, though it is not easy to see why in this view a charitable hospital should be liable for the negligence of its domestic servants but not of its medical staff.¹²⁷¹

The decision of the Court of Appeal in *Gold v Essex County Council*¹²⁷² in 1942, where the defendant hospital was held liable for the negligence of an employee

¹²⁶⁷ 188 Ill.2d 17, 719 N.E.2d 756 (Ill. 1999) (Supreme Court of Illinois).

¹²⁶⁸ 132 Cal.App.3d 332, 183 Cal.Rptr. 156 (Cal.App.4.Dist., 1982) (Court of Appeal of California, Fourth District).

¹²⁶⁹ Warren Swain, 'The development of medical liability in England and Wales' in Ewoud Hondius (ed), *The Development of Medical Liability* (Cambridge University Press, Cambridge, United Kingdom 2010) 37-38.

¹²⁷⁰ *Hillyer v The Governors of St. Bartholomew's Hospital* [1909] 2 KB 820, 825, [1909] WN 189 (Court of Appeal) (Farwell LJ), as cited Ibid 38.

¹²⁷¹ 1954 SLT 226, 234, 1954 SC 453, 476-477 (Court of Session (Inner House)).

¹²⁷² [1942] 2 KB 293, [1942] 2 All ER 237 (Court of Appeal).

radiographer, started the critical re-assessment period of hospital liability.¹²⁷³ By the time the Scottish ruling of *MacDonald* was given in 1954, the English courts had taken a different view on the question of vicarious liability about whether a hospital could be liable for the negligence of a competent doctor engaged by the hospital in the exercise of his professional skill.¹²⁷⁴ In *Cassidy v Ministry of Health*,¹²⁷⁵ Denning LJ in the Court of Appeal pointed out a different position from *Bartonshill Coal Co v McGuire*¹²⁷⁶ that health institutes are liable for the negligence of health practitioners employed by the institutes and they cannot escape their responsibility by delegating their performance to others, no matter whether the delegation is to a servant or to an independent contractor under a contract for services.¹²⁷⁷ Swain said that the new court position ‘coincided with the birth of the NHS’.¹²⁷⁸

The present general position in the UK is that except in special circumstances, a person is not liable for the negligence of an independent contractor.¹²⁷⁹ In England, following the establishment of the NHS Indemnity in 1990, clinical negligence indemnity coverage is provided for the employees of NHS, covering locums, students and other people with honorary contracts, conducting clinical trials and undergoing further professional training, etc. and the NHS will not be liable for any torts committed by a doctor who treats a patient under a private contract.¹²⁸⁰ The National Health Service Litigation Authority (NHS LA) was further established in 1995 to manage clinical claims against the NHS through 3 schemes: (a) the Clinical Negligence Scheme for Trusts (CNST) for medical incidents post-1 April 1995, (b) the Existing Liabilities Scheme for claims pre-1 April 1995, and (c) the Ex-RHA Scheme for clinical claims against the former Regional Health Authorities.¹²⁸¹ The CNST is open to all NHS providers and helps them spread the risk of indemnity by pooling financial resources and spread the costs of clinical negligence settlements

¹²⁷³ John G Fleming, ‘Developments in the English Law of Medical Liability’ (1958-1959) 12(3) *Vanderbilt Law Review* 633, 636 and Footnote 18.

¹²⁷⁴ *MacDonald v Glasgow Western Hospitals Board of Management* 1954 SLT 226, 228, 1954 SC 453, 456.

¹²⁷⁵ [1951] 2 KB 343, [1951] All ER 574 (Court of Appeal).

¹²⁷⁶ (1858) 3 Macq 300 (House of Lords).

¹²⁷⁷ [1951] 2 KB 343, 363, [1951] All ER 574 (Court of Appeal).

¹²⁷⁸ Swain (n 1269) 38.

¹²⁷⁹ Powell, Stewart and Jackson (eds) (2007) (n 391) 952 [13-059].

¹²⁸⁰ Murphy and Witting (n 1257) 637.

¹²⁸¹ United Kingdom, National Health Service Litigation Service, ‘Our Schemes’ <<http://www.nhs.uk/Claims/Schemes/>> accessed 29 September 2012.

over a period of time.¹²⁸² The CNST will not cover independent clinicians for adverse medical events and these independent contractors have to arrange their own insurance cover in respect of private and independent practices.¹²⁸³ It has been now made clear that the NHS is liable for the negligent acts of its full-time radiographers,¹²⁸⁴ house surgeons,¹²⁸⁵ nurses, doctors and surgeons,¹²⁸⁶ as well as part-time anaesthetists,¹²⁸⁷ but the NHS Indemnity does not cover independent contractors such as general practitioners, private-hospital employees, and other self-employed health practitioners.¹²⁸⁸

In the UK, exceptions exist where a person is liable for the negligence of an independent contractor. An example of the exceptions is where an employer has a non-delegable statutory duty and he or she cannot escape liability by merely appointing an independent contractor. Another exception involves consideration as to whether an employer has discharged his or her statutory duty or common law duty. In *Gwilliam v West Hertfordshire Hospital NHS Trust*,¹²⁸⁹ there were two issues before the Court of Appeal: whether the defendant hospital was under a duty to the claimant under s. 2(2) of the Occupiers' Liability Act 1957 to take such care as in all the circumstances was reasonable to ensure the claimant's safety when she paid a visit to a fair held at the hospital, and if affirmative, whether the hospital was in breach of that duty. With regard to the latter issue, Lord Woolf CJ said,

... I have no doubt that the hospital could fulfil its duty if it employed an appropriate, competent, independent contractor ... [I]f the hospital had not taken the steps which it should, in order to satisfy itself that the contractor was competent, the hospital would not have discharged the duty which it owed to the claimant. In deciding whether the contractor was competent the

¹²⁸² British Medical Association, *NHS Indemnity* 14-15, [4.7.1]

<<http://bma.org.uk/~media/Files/PDFs/Practical%20advice%20at%20work/Contracts/nhsmedicalindemnity.ashx>> accessed 22 June 2012.

¹²⁸³ United Kingdom, National Health Service Litigation Service, 'Clinical Negligence Litigation – A Very Brief Guide for Clinicians' <<http://www.nhs.uk/Clinicians/>> accessed 29 September 2012, [2].

¹²⁸⁴ *Gold v Essex County Council* [1942] 2 KB 293, [1942] 2 All ER 237 (Court of Appeal).

¹²⁸⁵ *Collins v Hertfordshire County Council* [1947] KB 598, [1947] 1 All ER 633 (High Court King's Bench).

¹²⁸⁶ *Cassidy v Ministry of Health* [1951] 2 KB 343, [1951] All ER 574 (Court of Appeal) (Denning LJ)

¹²⁸⁷ *Roe v Minister of Health* [1954] 2 QB 66, [1954] 2 All ER 131 (Court of Appeal).

¹²⁸⁸ Cambridge University Hospitals NHS Foundation Trust, Research and Development Department, 'Guidance Note – NHS Indemnity', 1
<http://www.cuh.org.uk/resources/word/research/guidance_note_NHS_Indemnity.doc> accessed 8 June 2012.

¹²⁸⁹ [2002] EWCA Civ 1041, [2003] QB 443 (Court of Appeal).

hospital had to take into account the nature of the task that the contractors ... was [*sic*] required to perform. This involved, in this case, being satisfied that [the independent contractor was] sufficiently experienced and reliable to be entrusted with ensuring that members of the public would be reasonably safe using [one of the amusement activities for the fair].¹²⁹⁰

The Court of Appeal in *Gwilliam* dismissed the appeal as the defendant hospital had discharged its duty when it inquired into the insurance position of the second defendant, an independent contractor, to confirm the latter's suitability to supply and operate an amusement activity in the hospital fair. Although *Gwilliam* was not a clinical negligence case, it provides a judicial hint as to how a health institute may discharge the duty of care owed to its patients when hiring independent contractors.

7.2.1.2.3 Agents

What will be the situation when a health practitioner who is an agent partially overlapping with the categories of both 'servant' and 'independent contractor'?¹²⁹¹ Courts have expanded the organizational responsibility of health institutes through the use of agency theory to make them take more control over the quality of healthcare service delivery and properly credential their healthcare staff, so as to offer more protection to patients.¹²⁹² In the US, the theory of ostensible agency allows courts to impose liability to health institutes for the torts of their participating health practitioners, even if the treating practitioner is an independent contractor.¹²⁹³ In some cases, health institutes may be found liable for their conduct in causing patients reasonably to believe that a health practitioner is the servant of a health institute where he or she is in fact not under the control of the institute or even not an employee of the institute. This is the theory of 'ostensible agency', which ignores both the test of control and salary payment as determinative of vicarious liability and also neglects the fact that the negligent health practitioner may be furthering his or her own business rather than the business of the health institutes.¹²⁹⁴ The

¹²⁹⁰ Ibid [12].

¹²⁹¹ Murphy and Witting (n 1257) 638.

¹²⁹² Richard R Balsamo and Max Douglas Brown, 'Risk Management' in Sanbar and others (eds) (2004) (n 988) 189-190.

¹²⁹³ Noah (n 1248) 1240.

¹²⁹⁴ Arther F Southwick, 'Vicarious Liability of Hospitals' (1960) 44(2) Marquette Law Review 153, 169.

Pennsylvania courts have identified two factors which are relevant to the theory of ostensible agency: (a) whether the patient looks to the institution, rather than the individual physician for care, and (b) whether a health maintenance organization ‘holds out’ the physician as its employee.¹²⁹⁵ In *Grewe v Mount Clemens Hospital*,¹²⁹⁶ the Supreme Court of Michigan ruled that where the claimant expected treatment from the staff of the defendant hospital, where the medical staff treating the claimant had no pre-existing relationship with him and were ostensible agents of the hospital, and where the claimant did not get any notice that the defendant doctor was an independent contractor instead of an employee of the hospital, the hospital could not escape liability for any negligence of the defendant doctor. In the UK, with the rising demand for skilled nurses and other health practitioners on top of the recruitment and retention difficulties, the NHS has hired more and more agency health practitioners.¹²⁹⁷ With the aforesaid NHS Indemnity, the NHS will no longer argue that doctors employed through a locum agency are not employees, as the NHS has indemnified them against liability for clinical negligence.¹²⁹⁸

7.2.1.3 Contributory Negligence

On other occasions, court may consider contributory negligence between health practitioners, health institutes, and patients. In a leading English case, *Butterfield v Forrester*, Ellenborough CJ said, ‘One person being in fault will not dispense with another’s using ordinary care for himself. Two things must concur to support this action, an obstruction in the road by the fault of the defendant, and no want of ordinary care to avoid it on the part of the plaintiff.’¹²⁹⁹ To establish contributory negligence, a defendant must plead¹³⁰⁰ and prove that the injury complained of was a result of the claimant’s self exposure to a particular risk, which contributed to the injury and was causally related to the claimant’s fault or

¹²⁹⁵ *Boyd v Albert Einstein Medical Center* 377 Pa.Super. 609, 619-620, 547 A.2d 1229, 1234 (Pa.Super., 1988) (Superior Court of Pennsylvania).

¹²⁹⁶ 404 Mich. 240, 273 N.W.2d 429 (Mich., 1978) (Supreme Court of Michigan).

¹²⁹⁷ Kim Hoque, Ian Kirkpatrick, Alex De Ruyter and Chris Lonsdale, ‘New Contractual Relationships in the Agency Worker Market: The Case of the UK’s National Health Service’ (2008) 46(3) *British Journal of Industrial Relations* 389, 394.

¹²⁹⁸ *British Medical Association* (n 1282) 5, [3.5.3]

<<http://bma.org.uk/~media/Files/PDFs/Practical%20advice%20at%20work/Contracts/nhsmedicalindemnity.ashx>> accessed 22 June 2012.

¹²⁹⁹ (1809) 11 East 60, 61, 103 ER 926 (Court of King’s Bench).

¹³⁰⁰ *Fookes v Slaytor* [1978] 1 WLR 1293, [1979] 1 All ER 137 (Court of Appeal).

negligence.¹³⁰¹ In *Pidgeon v Doncaster Royal Infirmary & Montagu Hospital NHS Trust*,¹³⁰² the defendant hospital gave a negligent negative report after taking a cervical smear from the claimant in 1988 and the claimant underwent extensive surgery for cervical cancer in 1997. The court held the claimant's repeated failure to undergo further smear tests despite warnings from her general practitioner was blameworthy and amounted to contributory negligence. Her damages were accordingly reduced by two thirds. In Canada, the Court of Appeal (Newfoundland) in *Brushett v Cowan*¹³⁰³ held that the patient consent form was not clear in allowing the surgeon to carry out a bone biopsy, but the patient claimant was contributorily negligent in failing to ask. The defendant surgeon was liable in battery and clinical negligence, with damages apportioned between the defendant and the claimant in a ratio of 80:20.

A court may also apportion liability among various disciplines of health practitioners, health institutes and others such as equipment manufacturers and/or equipment distributors. In the UK, the Court of Appeal in *Dwyer v Roderick*¹³⁰⁴ held that the defendant general practitioner was 45% liable in a serious drug error, whereas the defendant pharmacist and a partner of the general practitioner were 40% and 15% liable for their respective failures to spot the error. In *Jones v Manchester Corp.*,¹³⁰⁵ the defendant doctor was a newly qualified employee of the defendant health institute. She was allowed to use a drug during an operation without adequate supervision and the patient subsequently died. The Court of Appeal found that both defendants had contributed to the negligence and apportioned the liability between the health institute and the doctor in a ratio of 80:20.

In the context of telemedicine, as health institutes have potential corporate or vicarious liability,¹³⁰⁶ they need to consider a range of legal issues before deciding to provide telemedical services, including but not limited to malpractice, licensing and credentialing, informed consent, patient confidentiality and privacy, medical device problems, fraud and abuse, intellectual property, payments, and antitrust.¹³⁰⁷ Organizational readiness is required before the successful adoption of telemedicine.

¹³⁰¹ Murphy and Witting (n 1257) 194-195.

¹³⁰² [2002] Lloyd's Rep Med 130 (County Court (Sheffield)).

¹³⁰³ [1991] 2 Med LR 271 (Court of Appeal (Newfoundland)).

¹³⁰⁴ (1983) 80 LSG 3003, (1983) 127 SJ 806 (Court of Appeal).

¹³⁰⁵ [1952] 2 QB 852, [1952] 2 All ER 125 (Court of Appeal).

¹³⁰⁶ Edelstein (n 247) 64.

¹³⁰⁷ Ibid 63.

A survey in rural communities in Canada revealed that health institutes have to pay attention to several types of telemedicine readiness: (a) core readiness based on assessments of the existing shortcomings and the future needs, (b) staff engagement, (c) structural readiness for staff preparation, policy codification, adequate funding, making technology ready and influencing other stakeholders to adopt telemedicine, etc. and (d) contrary to organizational readiness, the non-readiness of health institutes such as people's lack of incentive to change from traditional to state-of-the-art practices.¹³⁰⁸ Telemedicine is changing and so is organizational readiness. Staff engagement and preparation in particular may help minimize the possible vicarious liability owed by health institutes. In the US, the Court of Appeals of Georgia in *Swindell v St. Joseph's Hospital* held that '[while a] hospital may be liable for the negligent acts of its servants and employees ... When a hospital yields control of its employees to a surgeon in the operating room and the surgeon exercises immediate personal supervision over these employees, then he becomes their master and their negligence during the course of the master servant relationship will be imputed to him.'¹³⁰⁹ In terms of structural readiness, advanced organizational planning of telehealth projects may require different policies at different stages and from different levels of decision makers.¹³¹⁰ Also, from a technical view, health institutes should also assess the readiness of a telematic network by using four criteria: necessity, transparency, security and confidentiality, and quality.¹³¹¹ Health institutes should also realize that a new telematic network is no longer a solution to well defined problems. It only serves as infrastructure to share a database through the collection and processing of personal data and serves as an information system for meeting future needs.¹³¹²

In telemedicine, with reference to the four general duties of health institutes as summarized in *Thompson v Nason Hospital*¹³¹³ above, health institutes providing telemedical services are responsible for properly retaining and overseeing the

¹³⁰⁸ Jennett and others (n 134) 138-143.

¹³⁰⁹ 161 Ga.App. 290, 291, 291 S.E.2d 1, 2 (Ga.App., 1982) (Court of Appeals of Georgia) (McMurray PJ).

¹³¹⁰ Shariq Khoja, Hammad Durrani and Ammad Fahim, 'Scope of Policy Issues for eHealth: Results from a Structured Review' (Conference on 'Making the eHealth Connection: Global Partnerships, Local Solutions', Bellagio, Italy, 13 July – 8 August 2008) 15 <http://www.ehealth-connection.org/files/conf-materials/Scope%20of%20Policy%20Issues%20for%20eHealth_0.pdf> accessed 8 June 2012.

¹³¹¹ Herveg and Pouillet (n 1217) 161-167.

¹³¹² Ibid 161.

¹³¹³ 527 Pa. 330, 339-340, 591 A.2d 703,707 (Pa., 1991) (Supreme Court of Pennsylvania).

performance of their health practitioners. A patient suffering from damage from telemedicine may claim that a health institute has failed in this aspect, or that it has breached its duty to provide safe and reliable equipment, or that the telemedical system was defective.¹³¹⁴ If a health institute were to try to avoid liability arising from ostensible agency, it could do whatever it could to inform patients that the health practitioners treating them online were not their employees.¹³¹⁵ However, this health institute still owes a non-delegable duty to its telemedicine patients, even in the absence of a contract between the institute and its tele-health practitioners.¹³¹⁶

7.2.2 Service Liability

The SIREN framework defines ‘service liability’ as that every health practitioner or health institute causing damage during the execution of the service contract may be held liable, and the introduction of telemedicine may invoke new forms of damages for which the current protection may not be sufficient.¹³¹⁷ Service liability for telemedicine is not widely covered in scholarly literature. Kilcullen compared product liability with the liability of medical services and said,

Enterprise liability can address similar problems posed by medical care. Medical treatment is the product of a network of trained individuals, many of whom have no contact with the patient [and] patients lack the bargaining power to negotiate all aspects of treatment, where, for example, they may consent to procedure without full comprehension of the procedure and its risks.¹³¹⁸

He advocated imposing a strict liability for medical services like the strict liability for products, as ‘consumers of health care are no less justified in seeking relief from the burden of proving fault than consumers of products, especially because health care providers claim a nobler motivation than profiting from the provided service.’¹³¹⁹ Under this model, all health practitioners are to be regarded as part

¹³¹⁴ Kuszler (n 5) 323-326.

¹³¹⁵ Landgreen (n 142) 377-378.

¹³¹⁶ Ibid.

¹³¹⁷ Rienhoff and others (eds) (n 188) 91.

¹³¹⁸ Jack K Kilcullen, ‘Groping for the Reins: ERISA, HMO Malpractice, and Enterprise Liability’ (1996) XXII (1) American Journal of Law & Medicine 7, 15.

¹³¹⁹ Ibid 11.

of a medical enterprise, and any health institutes providing traditional and telemedical healthcare services would exclusively be liable for any negligence associated with the services, as if the patients had been protected under product liability.¹³²⁰ However, such a strict liability model may not be fair enough for health institutes and practitioners. As what Denning LJ pointed out in *Roe v Minister of Health* in the UK, if liability were to be imposed on health institutes and practitioners for every medical misadventure, the court would be ‘doing a disservice to the community at large’.¹³²¹

7.2.3 Product Liability

7.2.3.1 Product Liability in General

Law helps boost consumer protection on products.¹³²² Product liability is an area of law to boost consumer protection by apportioning the risks inherent in consumer goods, and a choice has to be made with regard to which party should bear these risks: the victim, the manufacturers, or the country.¹³²³ In particular, manufacturers are subject to product liability claims for defects in the design or manufacturing of products or improper warning about dangers inherent in their use.¹³²⁴ Whereas a claimant in a clinical negligence claim has the burden of proof to show that a health practitioner has breached his or her duty of care, product liability is a strict liability where no proof of a manufacturer’s negligence is required, and a claimant is only required to demonstrate the existence of a defect in design or manufacturing or the manufacturer’s failure to warn.¹³²⁵ Distributors of hardware and software and equipment service companies may also have joint and several liability for technological failure embedded in their products. Some jurisdictions such as the UK, the US and the EU have measures to deal with patient safety in this regard. In the UK, the Consumer Protection Act 1987 (UK) provides that where two or more

¹³²⁰ McLean (2002) (n 716) 206-207.

¹³²¹ [1954] 2 QB 66, 86-87, [1954] 2 All ER 131 (Court of Appeal).

¹³²² Caryn Beck-Dudley, ‘Shifting the Burden of Proof in a Products Liability Case: *Anderson v. Somberg*’ (1982) 18(3) Idaho Law Review 539, 539.

¹³²³ Duncan Fairgrieve and Luis González Vaqué, ‘Introduction’ in Duncan Fairgrieve (ed), *Product Liability in Comparative Perspective* (Cambridge University Press, Cambridge, United Kingdom 2005) 1.

¹³²⁴ Aaron S Kesselheim and David M Studdert, ‘The Supreme Court, Preemption, and Malpractice Liability’ (2009) 360(6) The New England Journal of Medicine 559, 559.

¹³²⁵ Ibid.

persons are liable for the same damage due to defective products, their liability shall be joint and several.¹³²⁶ In the EU, the Council Directive 85/374/EEC imposes strict liability on manufacturers for defective products. In the Directive, a product is defined as defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected to be put, and the time when the product was put into circulation.¹³²⁷ A claimant shoulders the burden of proof to show two elements in order to establish the strict liability of a manufacturer: a defect in the product and damage or injury of a consumer.¹³²⁸ Article 7 of the Directive provides a series of defences for a defendant manufacturer if it proves that, for instance, it did not put the product into circulation¹³²⁹ or the defect only came into being after the product was put into circulation.¹³³⁰

7.2.3.2 Product Liability in Telemedicine

Product liability litigation in telemedicine has not been a frequent focus in the literature,¹³³¹ as health practitioners and health institutes are not subject to strict liability in general.¹³³² Telemedicine is considered a unique medical device as a common network is required for the use of multiple users, where individual health practitioners or patients cannot provide such a network infrastructure.¹³³³ In the context of risks, there are two schools of thought. One represents the idea that telemedicine as a new technology will reduce risks when health practitioners work through telemedicine together and provide more comprehensive treatment for patients. The other school believes that such a technology raises patient expectations and will therefore enhance litigation risks.¹³³⁴ In the US, the Centre for Devices and Radiological Health under the Food and Drug Administration has established guidelines for regulation of telemedicine devices to ensure the safety and

¹³²⁶ Section 2(5).

¹³²⁷ European Union, Council Directive 85/374/EEC of 25 July 1985 concerning liability for defective products, art 6.

¹³²⁸ *Ibid* art 1.

¹³²⁹ *Ibid* art 7(a).

¹³³⁰ *Ibid* art 7(b).

¹³³¹ Joseph P McMenamin, 'Does Products Liability Litigation Threaten Picture Archiving and Communication Systems and/or Telemedicine?' (1998) 11(1) *Journal of Digital Imaging* 21, 22.

¹³³² *Ibid* 28.

¹³³³ Landgreen (n 142) 375.

¹³³⁴ Pendrak and Ericson, 'Telemedicine may spawn long-distance lawsuits' (1996b) (n 147).

effectiveness of the use of telemedical devices in telemedicine related activities.¹³³⁵ Telemedicine being a state-of-the-art technology involves healthcare professionals, IT specialists, manufacturers of devices, and information services suppliers. Such coverage of different specializations may mean that even the most alert people involved in this technology may not absolutely ascertain its quality, efficacy and safety.¹³³⁶

7.2.3.2.1 Contributory Negligence?

In an adverse telemedicine event arising from a malfunctioned telemedical device, there are at least three potential defendants: the product manufacturer, the health practitioner, and the health institute, as they all have some degree of control over the medical equipment in the event.¹³³⁷ Claimants may also sue distributors of hardware and software and ISPs that facilitated the provision of telemedicine services. In such an event, which party will be responsible for the failure of a telemedicine technology?¹³³⁸ In theory, contributory negligence applies in such a case. In practice, however, it is not so simple to apply the doctrine of contributory negligence in the regime of strict liability. If damages were to be apportioned among parties in accordance with their degree of fault, how might this apportioning work when a patient claimant was contributorily negligent, whereas the defendant manufacturer was not at fault at all but would only assume strict product liability?¹³³⁹ Contributory negligence therefore means in practice that the claimant's damages will be reduced with reference to the extent to which his or her negligent act or omission has contributed to the injury.¹³⁴⁰

7.2.3.2.2 Health Practitioners / Institutes

Health practitioners and/or institutes may assume corporate liability due to a faulty system design of a telemedical device as such a design could have a greater

¹³³⁵ United States, Center for Devices and Radiological Health, Food and Drug Administration, *Telemedicine Related Activities* (11 July 1996; Updated August 5, 1997).

¹³³⁶ Caroline Laske, 'Legal Liability for Telemedicine and Healthcare Networking' in the ISHTAR Consortium (ed), *Implementing Secure Healthcare Telematics Applications in Europe* (IOS Press, Amsterdam, the Netherlands 2001) 78.

¹³³⁷ Ewell (n 769) 72.

¹³³⁸ Hodge, Gostin and Jacobson (n 572) 1469.

¹³³⁹ Emily Jackson (n 325) 568.

¹³⁴⁰ Ibid.

impact on the service quality.¹³⁴¹ In the US, the Court of Appeal of California in *Wickline v State*¹³⁴² said in dicta that third-party payors of health care services can be held legally accountable when a defectively designed or implemented system leads to medically inappropriate decisions. Kuszler said that in the context of telemedicine, *Wickline* helped to give a new meaning to ‘defects in design’ and ‘[is] more fruitful in terms of producing case law.’¹³⁴³

In terms of strict liability, a claimant may not be able to successfully sue a health practitioner or health institute for product liability in telemedicine. In *Hector v Cedars-Sinai Medical Center*, the Court of Appeal of California held that a hospital could not be held strictly liable for provision of an allegedly defective pacemaker to patients because it was only a provider of medical services, not a seller of products.¹³⁴⁴

7.2.3.2.3 Manufacturers

Manufacturers of healthcare telematics owe a duty of care to health practitioners, health institutes and patients.¹³⁴⁵ Can a manufacturer of telemedicine devices such as digital cameras be held liable for negligence in transmitting inaccurate patient data where the production of the cameras has met the industry standard? In the case of computer products, it has been argued that computer manufacturers sell products, not information.¹³⁴⁶ In the US, the Appellant Court of Illinois in *Black, Jackson and Simmons Ins. Brokerage Inc v International Business Machines Corp.*¹³⁴⁷ found that the information allegedly supplied by sellers was not supplied for the guidance of the claimant in its dealings with others. Laske has suggested that as health practitioners and health institutes are likely to have established a direct or indirect contractual relationship with manufacturers of telematics, a liability claim would be best brought against a manufacturer under the principles of contract law,¹³⁴⁸ instead of negligence. As for patients, in theory, they can sue manufacturers of telematics for negligence, but the development of case law

¹³⁴¹ Landgreen (n 142) 379.

¹³⁴² 192 Cal.App.3d 1630, 239 Cal. Rptr. 810 (Ct. App. 1986).

¹³⁴³ Kuszler (n 5) 323.

¹³⁴⁴ 180 Cal.App.3d 493, 225 Cal.Rptr. 595 (Cal.App.2.Dist. 1986) (Court of Appeal of California, Second District).

¹³⁴⁵ Laske (n 1336) 85.

¹³⁴⁶ McMenamin (n 1331) 27.

¹³⁴⁷ 109 Ill.App.3d 132, 440 N.E.2d 282 (Ill.App. 1 Dist., 1982) (Appellant Court of Illinois).

¹³⁴⁸ Laske (n 1336) 86.

regarding the pharmaceutical industry has demonstrated a shift from clinical negligence to strict liability, where the burden of proof has also been shifted from claimants in medical negligence claims to manufacturers in strict liability claims.¹³⁴⁹

With regard to the strict product liability, a defendant manufacturer in a claim involving a question about an allegedly defective telemedical device may argue the case based on a defence similar to article 7(e) of the EU Directive 85/374/EEC, which reads,

The producer shall not be liable as a result of this Directive if he proves ... that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.

The manufacturer may raise the defence that in view of the fast development of IT technologies, the state of scientific and technical knowledge when the manufacturer put the defective telemedical device into circulation could not help identify the existence of the defect.¹³⁵⁰

The European defence is slightly different from the British version.¹³⁵¹ In the UK, section 4(1)(e) of the Consumer Protection Act 1987 (UK) states,

[I]t shall be a defence ... that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.

The wider scope of the Consumer Protection Act 1987 (UK) enabled a defendant manufacturer to have a defence when other manufacturers were also equally ignorant about how to detect the defect in question, even if the defect was discoverable.¹³⁵²

The difference between the two versions was settled in the European Court of Justice, which concluded that section 4(1)(e) of the Consumer Protection Act (UK) was capable of being interpreted in a way to be consistent with article 7(e) of the EU

¹³⁴⁹ Ibid 87.

¹³⁵⁰ European Union, Council Directive 85/374/EEC (n 1327) art 7(e).

¹³⁵¹ Emily Jackson (n 325) 568.

¹³⁵² Ibid.

Directive 85/374/EEC. In *A v National Blood Authority (No. 1)*, Burton J said, ‘Although the UK Government has not amended Section 4(1)(e) of the [Consumer Protection Act] so as to bring it in line with the wording of the Directive, there is thus binding authority of the European Court that it must be so construed.’¹³⁵³

In *Commission of the European Communities v United Kingdom (Re the Product Liability Directive)* (Case C-300/95),¹³⁵⁴ the European Court of Justice pointed out that article 7(e) of the EU Directive is not specifically directed at industrial practices and safety standards but refers to the state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the defective product in question was put into circulation. The defence contemplates the objective state of scientific and technical knowledge of which the producer is presumed to have been informed, rather than the actual or subjective state of knowledge. Also, it is implicit in the wording of article 7(e) that the relevant scientific and technical knowledge must have been accessible at the time when the product was put into circulation. So, for a successful defence under article 7(e), a defendant manufacturer must prove that at the time when the product was put into circulation, it was not able to discover the existence of the defect according to the objective state of scientific and technical knowledge, including the most advanced level of such knowledge. On the other hand, in order to successfully plead the case against the defendant manufacturer, a claimant has to show that the relevant scientific and technical knowledge must have been accessible at the time when the defendant put the defective product into circulation.¹³⁵⁵

7.2.3.2.4 Distributors of Software

Distributors of software may be subject to a claim against a defective telemedical device arising from software problems. In Europe, it was not certain whether Directive 85/374/EEC would apply to software.¹³⁵⁶ This loophole is now dealt with by Directive 93/42/EEC on medical devices, which aims at harmonizing the laws, regulations and administrative provisions in force in the EU member states with a view to the safety, health protection, performance characteristics of medical

¹³⁵³ [2001] 3 All ER 289 (High Court Queen’s Bench), [21].

¹³⁵⁴ [1997] 3 CMLR 923.

¹³⁵⁵ Ibid 940.

¹³⁵⁶ Laske (n 1336) 80.

devices, certification and inspection duties,¹³⁵⁷ as well as providing patients, users and third parties with a high level of protection and attaining improved levels of protection attributed to them by manufacturers in the member states.¹³⁵⁸ In Directive 93/42/EEC, software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application has been included in the definition of a medical device.¹³⁵⁹ It requires member states to ensure that medical devices may be placed on the market and put into service only if they comply with the safety requirements as set out in Annex I of the Directive.¹³⁶⁰

McMenamin argued that to bring legal actions against manufacturers or distributors of software and hardware, etc. would extend the concept of ‘computer malpractice’¹³⁶¹ to the concept of ‘transmission malpractice’.¹³⁶² However, the courts’ positions about ‘computer malpractice’ are not uniform,¹³⁶³ let alone ‘transmission malpractice’. In the US, the Court of Appeals of Indiana in *Data Processing Services, Inc. v L.H. Smith Oil Corporation*¹³⁶⁴ held that a contract for developing computer programme was not a sale of ‘goods’ but a contract for the computer programmer’s skills and knowledge, even though the computer programme would be finally preserved by means of magnetic tape, floppy disk, hard disk or hardware alike, and that the appellant computer programmer which held itself out as possessing skills and qualifications necessary to design and develop the computer programme in question breached the implied reasonable standard to carry out the duty for which it contracted. In *Chatlos Systems, Inc. v National Cash Register Corp.*,¹³⁶⁵ the District Court of New Jersey declined acceptance of a novel concept of a new tort called ‘computer malpractice’. In *Rogers Merchandising, Inc. v Bojangles’ Corp.*,¹³⁶⁶ the District Court of Illinois also held that a cause of action for malpractice against an advertising or marketing agency was a novel proposition and it was not recognized by Illinois courts.

¹³⁵⁷ European Union, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Recital 2.

¹³⁵⁸ Ibid Recital 5.

¹³⁵⁹ Ibid art 1(2)(a).

¹³⁶⁰ Ibid arts 2 and 3.

¹³⁶¹ Sue Ganske Graziano, ‘Computer Malpractice - A New Tort on the Horizon’ (1991) 17(1) Rutgers Computer and Technology Law Journal 177.

¹³⁶² McMenamin (n 1331) 27.

¹³⁶³ Graziano (n 1361) 177.

¹³⁶⁴ 492 N.E.2d 314, 1 UCC Rep.Serv.2d 29 (Ind.App. 4 Dist., 1986) (Court of Appeals of Indiana, Fourth District).

¹³⁶⁵ 479 F.Supp. 738, 27 UCC Rep.Serv. 647 (D.C.N.J., 1979) (District Court of New Jersey).

¹³⁶⁶ Not reported in F.Supp., 1989 WL 6391 (N.D. Ill. 1989) (District Court of Illinois).

There are other technical considerations when a claimant tries to sue a distributor of software. First, the claimant might argue that the technology used in telemedicine is a product and is subject to strict liability,¹³⁶⁷ as demonstrated by the fact that the EU Directive 93/42/EEC has included software into the definition of a medical device.¹³⁶⁸ While this argument may be sound in Europe, whether it is equally sound in other countries such as the US is problematic. In the US, the position under case law is not uniform. In *Data Processing Services, Inc. v L.H. Smith Oil Corporation*¹³⁶⁹ above, the Court of Appeals of Indiana held that transaction to provide a computer programme was not a sale of goods; whilst in *Winter v G.P. Putnam's Sons*,¹³⁷⁰ the Court of Appeal of the US said in dicta that software could be subject to strict liability.

Another technical issue is the emerging standards. A defendant distributor of software and/or a defendant manufacturer can argue that its digital products meet industry standards.¹³⁷¹ In fact, industry standards are emerging, too. For instance, the Digital Imaging and Communication in Medicine, or commonly known as DICOM, developed by the American College of Radiology and National Electrical Manufacturers Association to address five general application areas including network image management, network image interpretation management, network print management, imaging procedure management, and off-line storage media management,¹³⁷² has been constantly updated and extended.

7.2.3.2.5 ISPs

While health practitioners and/or health institutes may or may not be liable for any harm arising from a technological failure in telemedicine, ISPs may be liable if in the process of data transmission in a telemedical practice, the confidentiality, integrity or availability of data is compromised.¹³⁷³ It is arguable that ISPs could escape liability on public policy grounds, as no one would be willing to provide

¹³⁶⁷ *McMenamin* (n 1331) 28.

¹³⁶⁸ Art 1(2)(a).

¹³⁶⁹ 492 N.E.2d 314, 1 UCC Rep.Serv.2d 29 (Ind.App. 4 Dist., 1986) (Court of Appeals of Indiana, Fourth District).

¹³⁷⁰ 938 F.2d 1033, 1036, 60 USLW 2068 (C.A.9 (Cal.), 1991) (United States Court of Appeals, Ninth Circuit).

¹³⁷¹ *McMenamin* (n 1331) 27.

¹³⁷² W Dean Bidgood, Steven C Horii, Fred W Prior and Donald E Van Syckle, 'Understanding and Using DICOM, the Data Interchange Standard for Biomedical Imaging' (1997) 4(3) *Journal of the American Medical Informatics Association* 199, 202.

¹³⁷³ *Laske* (n 1336) 90.

Internet services at a reasonable cost with a view to the possible high level of liability resulted from intermittent failures of information transmission.¹³⁷⁴ This is a pragmatic and commercial consideration. In theory, if ISPs providing transmissions are to be held wholly or jointly liable for any medical malpractice owing to a poor transmission of patient information, the telecommunications market will be likely to be reluctant to offer connections between and among health practitioners and patients.¹³⁷⁵ In actual practice, ISPs have tried to limit their liability and define the quality of goods or services they provide through the use of contractual provisions. For instance, ISPs in Australia¹³⁷⁶ and Hong Kong¹³⁷⁷ have imposed similar contractual terms to expressly spell out that their services are not fault free and they cannot guarantee uninterrupted service or the quality of the service. A telemedicine service provider in Canada has recently provided some useful practical tips to its members to tackle the fluctuating quality of Internet services, such as making a backup plan in case of a ‘protracted outage’ of the Internet connection for a clinical practice and not to run multiple telemedicine videoconferencing sessions over an Internet connection if the technical design can only support one session.¹³⁷⁸

7.2.4 Contractual Liability

7.2.4.1 Contract Liability in General

At common law, a contractual relationship may not exist between a health practitioner and a patient, as revealed in the relationship between the NHS in the UK and its non-private patients.¹³⁷⁹ Even if there is a contractual relationship, the Court of Appeals of Georgia in the US in *Anderson v Houser* held that the existence of such a contractual relationship requires the express or implied consent of both parties.¹³⁸⁰

¹³⁷⁴ Landgreen (n 142) 375.

¹³⁷⁵ Magenau (n 499) 38.

¹³⁷⁶ TPG, ‘Service Descriptions and Terms’ <http://www.tpg.com.au/terms_conditions/ull_no_voip> accessed 10 May 2012.

¹³⁷⁷ ‘Vodafone – Terms and Conditions’ <http://www.expansys.com.hk/i/drv/vodafone_terms.pdf> accessed 10 May 2012.

¹³⁷⁸ Ontario Telemedicine Network, *Technical Service Level Agreement* (Version 5.2; October, 2011) 19-20

<[http://otn.ca/files/member_portal/Technology/Technical%20Service%20Level%20Agreement%20\(TSLA\).pdf](http://otn.ca/files/member_portal/Technology/Technical%20Service%20Level%20Agreement%20(TSLA).pdf)> accessed 8 June 2012.

¹³⁷⁹ Powell, Stewart and Jackson (eds) (2007) (n 391) 897 [13-003].

¹³⁸⁰ 240 Ga.App. 613, 617, 523 S.E.2d 342, 346 (Ga.App., 1999) (Court of Appeals of Georgia).

In practice, there is not always a written contract between the parties.¹³⁸¹ Instead of relying on any written contractual terms, a contractual relationship may be established by the implied conduct of both parties, e.g. a patient's consent to pay medical fees in return for a doctor's medical services and the doctor's willingness to provide healthcare services in 'a professional manner with a reasonable degree of diligence and competence'.¹³⁸² Also, an action in contract is not common. In the UK, Peter Pain J in *Thake v Maurice* said, '[The present] case differs from the ordinary 'medical negligence' case in that the plaintiffs put their case boldly in contract.'¹³⁸³

7.2.4.2 Contract Liability in Telemedicine

In telemedicine, the rare existence of an express contract between health practitioners, health institutes and patients in traditional practices does not necessarily mean that they can pay no attention to the contractual liability in the cyber environment, as in some jurisdictions such as Switzerland, Germany, Belgium,¹³⁸⁴ France¹³⁸⁵ and China,¹³⁸⁶ the health practitioner-patient relationship is traditionally a contractual one. In fact, home telemedicine, for example, has turned patients and their family members into active co-participants in the healthcare service delivery,¹³⁸⁷ which may have created a change to the conventional health practitioner-patient relationship. Also, other than patients and their family members, cross-border telemedicine involves health practitioners, health institutes, ISPs and product manufacturers.¹³⁸⁸ In view of the fact that statutory rules and regulations are not available in every country, making a contract to specify the duties, responsibilities and liabilities of parties involved in a telemedicine practice at least provides a handy solution to safeguard the interests of various parties.¹³⁸⁹

¹³⁸¹ Chew (n 446) 19 [2.20].

¹³⁸² Ibid.

¹³⁸³ [1986] QB 644, 657, [1986] 1 All ER 479 (Court of Appeal).

¹³⁸⁴ Grossen and Guillod (n 474) 5.

¹³⁸⁵ European Commission, Directorate General Information Society (2009) (n 163) 43.

¹³⁸⁶ Jingwei Liu and Maonian Li, *Legal Study on Doctor-Patient Relationship* (Citic Publishing House, Beijing, China 2002) (柳經緯及李茂年, 醫患關係法論 (中信出版社, 中國北京 2002); *liǔ jīng wěi jí lǐ mào nián , yī huàn guān xì fǎ lùn (zhōng xìn chū bǎn shè , zhōng guó běi jīng 2002)*) 4-5.

¹³⁸⁷ Kluge (n 1080) e3.

¹³⁸⁸ Nakajima, 'Cross-Border Medical Care and Telemedicine' (2012) (n 139) 46.

¹³⁸⁹ Laske (n 1336) 61.

7.2.4.2.1 Electronic Contracting

With the increasing popularity of online transactions, electronic contracting provides an alternative to parties in cross-border telemedicine on top of paper contracts and can be made mainly by using the Internet and through emails.¹³⁹⁰ Contracts through the World Wide Web are instantaneous, where an offer can be made through an online form, and an acceptance may follow through email, delivery of products or an online confirmation notice on the website.¹³⁹¹ In the UK, Denning LJ's statement given in the Court of Appeal in *Entores Ltd v Miles Far East Corp* can be analogously applied in web contracts, where he said,

So far as Telex messages are concerned, though the dispatch and receipt of a message is not completely instantaneous, the parties are to all intents and purposes in each other's presence just as if they were in telephonic communication, and I can see no reason for departing from the general rule that there is no binding contract until notice of the acceptance is received by the offeror.¹³⁹²

To follow the reasoning of Denning LJ above and to make an analogy with telex, express and instantaneous contracts in telemedicine through health-related websites may likely be formed when details such as the nature of the telemedical services, requirements for patients' informed consent, express disclaimers and waivers of liability, etc. are shown to potential patients online.¹³⁹³

As for the concern about the uncertainty as to when an email contract is concluded, Ong has proposed insertion of a contractual clause into an email contract, asserting that a contract exists only upon receipt of an acceptance.¹³⁹⁴ A recent Australian case has also provided a legal reference. In *Olivaylle Pty Ltd v Flottweg GMBH & Co KGAA (No 4)*,¹³⁹⁵ one of the issues before the Federal Court of Australia concerned the application of the postal rule in electronic contracting through emails.

¹³⁹⁰ Paul Stephenson and Alisa Kwan, *Cyberlaw in Hong Kong* (2nd edn, LexisNexis, Hong Kong 2007) 389.

¹³⁹¹ Ong (n 577) 106.

¹³⁹² [1955] 2 QB 327, 337, [1955] 2 All ER 493 (Court of Appeal).

¹³⁹³ Blum (n 67) 438.

¹³⁹⁴ Ong (n 577) 104-105.

¹³⁹⁵ [2009] FCA 522, (2009) 255 ALR 632 (Federal Court of Australia).

After making reference to a scholarly article and case law including but not limited to *Entores*¹³⁹⁶ above, Logan J said,

Experience suggests that email is often, but not invariably, a form of near instantaneous communication ... I consider that there are analogies to be drawn with the way the law developed in relation to telex communications in an earlier era where what I have termed “the instantaneous communication rule” came to be adopted, perhaps at the expense of scientific precision but not so in relation to common commercial understanding. Thus, by analogy with cases concerning the position with what were, or were treated as, other forms of instantaneous communication, I consider that the [email] contract was made where the acceptance was received.¹³⁹⁷

In drafting online contracts, Laske has advised a list of contractual headings specific to telemedicine: inclusion of all parties and not just institutional parties, objectives of the telemedical practices, delineation of each party’s duties and responsibilities including which part(ies) should be directly liable to patients, parties’ adherence to specific telemedical procedures, how to manage medical confidentiality, security and data protection including policies of access to data and transmission of data, audit trails, what would constitute evidence in court, damages, and limitation, etc.¹³⁹⁸ Furthermore, the choice of law and how parties may resolve disputes, e.g. going to court or through private proceedings like alternative dispute resolutions, should also be considered while drafting the contract.¹³⁹⁹ A review of the failure to use telephone lines to develop telemedicine in the 1960s and 1970s¹⁴⁰⁰ has also pointed to the importance of specifying staff training requirements and spelling out technical specifications such as image quality in the contract. Oren and colleagues have advocated the creation of an electronic contracting language to formalize different contract clauses developed over the years in different jurisdictions, so as to help

¹³⁹⁶ [1955] 2 QB 327, [1955] 2 All ER 493 (Court of Appeal).

¹³⁹⁷ *Olivaylle Pty Ltd v Flottweg GMBH & Co KGAA (No 4)* [2009] FCA 522, (2009) 255 ALR 632 (Federal Court of Australia), [25].

¹³⁹⁸ Laske (n 1336) 61.

¹³⁹⁹ Ann H Nevers, ‘Medical Malpractice Arbitration in the New Millennium: Much Ado About Nothing’ (2000-2001) 1(1) Pepperdine Dispute Resolution Law Journal 45, 82.

¹⁴⁰⁰ J R Maclean, L D Ritchie and A M Grant, “Telemedicine: ‘communication’ by any other name?” (1997) 47(417) British Journal of General Practice 200, 200.

design a system that allows monitoring of any breach of contract, establishing who should be responsible for the breach, and supporting decision making and action planning.¹⁴⁰¹

However, an ‘across state line’ or a cross-border telemedicine contract may not protect the full interest of patients, as some contractual terms may not be enforceable in certain jurisdictions, not to mention that some private health practitioners and small health institutes may not bother to conclude such a contract with other parties.¹⁴⁰² In the US, the Supreme Court of Oklahoma in *Cannon v Lane*¹⁴⁰³ ruled that a contract between the state and a health maintenance organization with a contractual term requiring all future controversies to be submitted to arbitration is contrary to public policy and unenforceable. The Supreme Court of Arizona in *Broemmer v Abortion Services of Phoenix, Ltd*¹⁴⁰⁴ held that a contract of adhesion containing a contractual provision asking patients to arbitrate malpractice claims and to waive their right to jury trial was unenforceable. The Court of Appeal of California in *Wheeler v St. Joseph Hospital*¹⁴⁰⁵ elaborated that the term ‘adhesion contract’ refers to standardized contract forms of goods and services where a consumer does not have a realistic opportunity to bargain and under such conditions, the consumer has no choice. He or she can either take the goods or services by acquiescing in the standard form contract or forget the desired goods and services.

7.3 Criminal Liability

Cybercrime has become one of the serious concerns of governments and organizations. In the US, Mike Mullen, the former Chairman of the Joint Chiefs, said, ‘We are vulnerable in the military and in our governments, but I think we’re most vulnerable to cyber attacks commercially. This challenge is going to significantly increase ...’¹⁴⁰⁶ In the UK, in *R v Gold (Stephen William) and R v Schifreen (Robert*

¹⁴⁰¹ Nir Oren, Sofia Panagiotidi, Javier Vázquez-Salceda, Sanjay Modgil, Michael Luck and Simon Miles, *Towards a Formalisation of Electronic Contracting Environments* (Association for the Advancement of Artificial Intelligence, California, United States 2008) <<http://calicum.dcs.kcl.ac.uk/1282/1/oren.pdf>> accessed 17 June 2012, 1-2.

¹⁴⁰² Laske (n 1336) 61.

¹⁴⁰³ 867 P.2d 1235, 1240, 16 Employee Benefits Cas. 2783, 1993 OK 40 (Okla., 1993) (Supreme Court of Oklahoma).

¹⁴⁰⁴ 173 Ariz. 148, 150, 840 P.2d 1013, 1015 (Ariz., 1992) (Supreme Court of Arizona).

¹⁴⁰⁵ 63 Cal.App.3d 345, 356, 133 Cal.Rptr. 775, 783 (Cal.App.4.Dist. 1976) (Court of Appeal of California, Fourth District).

¹⁴⁰⁶ Geoff Colvin, ‘Admiral Mike Mullen: After a 43-Year Military Career, the Former Joint Chiefs Chairman Is as Outspoken as Ever.’ (2012) 165(7) *Fortune* 500 (Asia Pacific edn, 21 May 2012) 43, 44.

Jonathan),¹⁴⁰⁷ the defendants gained unauthorized access to a computer network by entering a number and password through a keyboard. The computer cleared the defendants' number and password after checking the correct ones automatically, and the accurate set of secret codes was only stored in the computer in an extremely short period of time and was then expunged from the computer memory. The defendants used a dishonest trick to gain unauthorized access into the computer and were charged with forgery, contrary to the Forgery and Counterfeiting Act 1981 (UK). The House of Lords held that the defendants committed no offence, as the Act required the storage of information for some appreciable time, while the computer only used the number and password momentarily to confirm the user's authority. Following this case, people started to realize the inadequacy of criminal law at the time to combat computer crimes.¹⁴⁰⁸

In the context of telemedicine, people's concern about the quality of health care over the Internet has been extended to the potential for fraudulent acts and other illegal purposes such as acquiring drugs for non-medical use¹⁴⁰⁹ and unauthorized interception of patient data and information. With regard to the risks of online prescription, in order to strike a balance between the development of telepharmacy and blocking the risks that patients provide *carte blanche* for mountebanks and opportunists, Mills advocated extending legal prohibitions to deter doctors from prescribing drugs online to patients with whom they have had no previous face-to-face contact and have only had a patient history taken from online questionnaires. He further suggested the following elements for inclusion into the ethical code of conduct issued by health professional bodies: the pre-existence of a health practitioner-patient relationship arising from actual face-to-face clinical examination, verifiable patient identity before commencement of online services, health practitioners being licensed in the patients' jurisdictions, and application of all normal rules relating to record-keeping and confidentiality.¹⁴¹⁰ With such measures, it is hoped that occurrence of incidents like the unlicensed defendant doctor's improper e-

¹⁴⁰⁷ [1988] AC 1063, [1988] 2 All ER 186 (House of Lords).

¹⁴⁰⁸ Stephenson and Kwan (n 1390) 99.

¹⁴⁰⁹ Ewell (n 769) 69.

¹⁴¹⁰ Simon Mills, 'Online prescribing: principles, problems and policing' (2003) 9 Medical-Legal Journal of Ireland 36, 41-42.

prescribing to the victim without first seeing him in *Hageseth v Superior Court*¹⁴¹¹ in the US can be minimized.

Patient data protection is another important issue in the practice of telemedicine. To safeguard patients' interests against criminal acts, measures at individual, institutional and legal levels have been proposed. At the individual level, Nevins and Pion suggested patients select and use services of those health practitioners and institutes who are trustworthy in the healthcare field, as reputable pre-Internet practitioners and institutes are still reputable on the Internet.¹⁴¹² Studies found that cyber criminals have characteristics of being young, well-educated and technologically sophisticated, and cyber stalkers in particular aim to seek victims who are inexperienced Internet users.¹⁴¹³ As patients and health practitioners are not often trained IT specialists, in the eyes of cyber criminals, they become 'inexperienced' users in the provision of telemedical services. So, at the institutional level, health practitioners and institutes are obliged to safeguard electronic health databases against computer crimes including hacking, which is committed normally in two forms. Both involve unauthorized access to computer data on others' computers and the difference between the two is whether the information being hacked is available to the public on a fee basis or not available to the public.¹⁴¹⁴ Transmission of health information over the Internet will also be subject to risks of unauthorized interception or receipt. Oberbroeckling has advised that implementation and regular review of policies of privacy, security and data integrity together with effective enforcement mechanisms of the policies are essential for a safe system. A good privacy policy outlines detailed policy and procedures to limit access to health records and a well-drafted security policy will help ensure the integrity of the data stored electronically. Unless sufficient precautions are in place to protect patients' data from loss, theft, misuse, alteration or destruction, a privacy policy restricting access to data on paper will not be effective in patient data protection. A data integrity policy is also required to control the input and output procedures and ensure the accuracy and completeness of the data collected and stored. Last but not least, enforcement mechanisms help health

¹⁴¹¹ 150 Cal.App.4th 1399, 59 Cal.Rptr.3d 385 (Cal.App. 1 Dist., 2007) (California Court of Appeal, First District).

¹⁴¹² Nevins and Pion (n 1240) 207.

¹⁴¹³ Lynne Roberts, 'Jurisdictional and definitional concerns with computer-mediated interpersonal crimes: An Analysis on Cyber Stalking' (2008) 2(1) International Journal of Cyber Criminology 271, 278-279.

¹⁴¹⁴ Stephenson and Kwan (n 1390) 103.

practitioners and institutes check the compliance level and make corrective or improvement actions accordingly.¹⁴¹⁵ At the legal level, in addition to the common law requirements, legislation is enacted to tackle cybercrime. To cite a few examples, the Health Insurance Portability and Accountability Act 1996 in the US provides that a person who knowingly discloses or acquires individually identifiable health information in violation of the law and regulations is subject to a fine of up to US\$50,000 and a maximum of one year of imprisonment.¹⁴¹⁶ In the UK, the Computer Misuse Act 1990 (UK) stipulates that it is an offence if a person causes a computer to perform any function with intent to secure access to any programme or data held in any computer without authorization¹⁴¹⁷ and an offender is subject on summary conviction or conviction on indictment to imprisonment, or a fine or both.¹⁴¹⁸

7.4 Chapter Conclusion

Health practitioners and institutes face organizational challenges when they provide telemedical services. On top of traditional considerations including but not limited to direct liability and vicarious liability, they need to think about other issues such as medical liability, licensing and credentialing, electronic signatures and online patient consent, cyber safeguards for EHRs, and other criminal risks in the planning stage of telemedicine to assess organizational readiness. Product liability is also a legal challenge as telemedical devices will inevitably involve ISPs in addition to traditional parties such as product manufacturers, where health practitioners and/or institutes do not have much control over the quality of the transmission of electronic patient data. Unfortunately, the service quality and reliability of ISPs will have a direct bearing on the health service quality, as any missing patient data or poor quality of transmission will affect clinical judgements as evidenced in the case of teledermatology. Criminal liability in telemedicine creates a new challenge as well. In traditional practice, the number of health practitioners involved in criminal proceedings is not so alarming, as revealed by the study of Ferner & McDowell that only 85 criminal prosecutions were found in the UK in the two centuries between

¹⁴¹⁵ Laura J Oberbroeckling, 'e-Health and the Law' in Goldstein (ed) (2000) (n 1240) 417-418.

¹⁴¹⁶ 42 U.S.C. §1320d-6(a).

¹⁴¹⁷ Section 1(1).

¹⁴¹⁸ Section 1(3).

1795 and 2005,¹⁴¹⁹ and by Zhang's observations that a large number of infringement behaviours in China affecting peoples' life and health were not severe enough to be pursued through the criminal channel.¹⁴²⁰ However, telemedicine runs in the virtual space, the 'invisible enemy' that patients, health practitioners and institutes face online is cyber criminals who are young, well educated and technologically sophisticated. Disastrous events may occur if health practitioners and institutes do not pay sufficient attention to protect their EHRs and the telemedical infrastructure and devices.

¹⁴¹⁹ Ferner and McDowell (n 226) 312 and Table 2.

¹⁴²⁰ Yue Zhang (2004) (n 227).

CHAPTER 8

Medico-Legal Aspects of Cross-Border Telemedicine Practice between Hong Kong and China

[S]imply doing more of what we have always done
is no longer an option. We need to do things differently.
We need to radically transform the way we deliver services.
Innovation is the way – the only way – we can meet these challenges.
— David Nicholson¹⁴²¹

8.1 Chapter Summary

‘Ideally, our medical care should be as portable as our medical conditions’¹⁴²² In practice, patients and health practitioners in ‘across state lines’ and cross-border telemedicine have to be vigilant, as on top of risks such as patient data protection and failure of telemedical devices that are commonly known in telehealth, other medical errors due to differences in legal standards, standards of care and the philosophy of healthcare delivery may arise.¹⁴²³ Cultural disparity is also an issue.¹⁴²⁴ In this chapter, cross-border telemedicine practice between Hong Kong and China will be examined to showcase how the differences of the healthcare and legal systems between the two territories may affect the dynamics of the provision of cross-border telemedicine and see how the differences may have a bearing on the medico-legal liability. Not all the nine areas of the SIREN liability will be addressed under separate headings in this chapter as has been done in Chapters 4-7, as in practice, telemedicine health institutes and practitioners have to take a robust approach to collectively safeguard themselves against organizational liability, service liability, product liability and contractual liability, in addition to other considerations on medical liability, patient safety and patient data protection.

8.2 A Brief on the Health Systems of Hong Kong and China

The healthcare systems of Hong Kong and China differ in a number of ways. In terms of healthcare financing, the Hong Kong Government has subsidized

¹⁴²¹ United Kingdom, Department of Health, *Innovation health and wealth: Accelerating adoption and diffusion in the NHS* (Department of Health, London, updated June 2012) 4.

¹⁴²² Merrell (2004) (n 1238) 144.

¹⁴²³ Kluge (n 1080) e2.

¹⁴²⁴ Michel (n 173) 305-306.

the general public across-the-board for over 90% of healthcare expenditures,¹⁴²⁵ and it has been a long established public healthcare policy that no one will be denied adequate medical care because of lack of money and this policy has been legislated in the Hospital Authority Ordinance.¹⁴²⁶ Public health expenditure in 2010 was expected to be 3.3% of GDP and is projected to be 5.5% in 2033.¹⁴²⁷ In China, access to health services is still inequitable¹⁴²⁸ in both urban¹⁴²⁹ and rural areas.¹⁴³⁰ A large portion of Chinese people do not have access to healthcare services because of financial barriers.¹⁴³¹ The total health expenditure in China increased from 3.17% of GDP in 1980 to 5.55% in 2004 and dropped gradually to 4.52% in 2007. In that period of time, the private share more than doubled from 21.2% of total health expenditure in 1980 to 53.6% in 2004 and went down to 45.2% in 2007, whereas the government share plummeted from 36.2% of total healthcare expenditure in 1980 to 17.1% in 2004 and rose to 20.3% in 2007.¹⁴³² The shift in the public spending percentage has aggravated poverty issues in China. According to the First National Health Services Survey conducted in 1998, the issue of diseases and injuries in China was ranked the second major poverty generator.¹⁴³³ The Third National Health Services Survey in 2003 revealed that 32% of rural patients and 47% of urban patients chose self treatment without seeing a doctor.¹⁴³⁴ In the context of health services, a survey found that although hospital care in Hong Kong was good in general in the areas of timeliness, professional knowledge and staff competency, patients had high expectations and persistently requested prompt and competent services.¹⁴³⁵ In China, Ma and colleagues criticized that through lack of an effective

¹⁴²⁵ Peter P Yuen, 'Health Care Financing in Hong Kong: A Case for Tax-based Financing' (1999) 14 *International Journal of Health Planning and Management* 3, 6.

¹⁴²⁶ Hong Kong, Hospital Authority Ordinance (Cap 113), section 4(d).

¹⁴²⁷ Hong Kong, Food and Health Bureau, *Synopsis of Healthcare Financing Studies: Projection of Hong Kong's Healthcare Expenditure* (2008) 6, Table 1
<http://www.fhb.gov.hk/beStrong/files/consultation/projectthealthexp_eng.pdf> accessed 16 June 2012.

¹⁴²⁸ Tang and others (2008) (n 109).

¹⁴²⁹ Wang, Gericke and Sun (2009) (n 110).

¹⁴³⁰ Zhou and others (2011) (n 111).

¹⁴³¹ Jin Ma, Mingshan Lu and Hude Quan, 'From A National, Centrally Planned Health System To A System Based On The Market: Lessons From China' (2008) 27(4) *Health Affairs* 937, 941.

¹⁴³² Jens Leth Hougaard, Lars Peter Østerdal and Yi Yu, 'The Chinese Healthcare System: Structure, Problems and Challenges' (2011) 9(1) *Applied Health Economics and Health Policy* 1, 4 and Table I.

¹⁴³³ Yuanli Liu, Keqin Rao and William C Hsiao, 'Medical Expenditure and Rural Impoverishment in China' (2003) 21(3) *Journal of Health, Population and Nutrition* 216, 218.

¹⁴³⁴ Meina Liu, Qiuju Zhang, Mingshan Lu, Churl-Su Kwon and Hude Quan, 'Rural and Urban Disparity in Health Services Utilization in China' (2007) 45(8) *Medical Care* 767, 770, Table 2.

¹⁴³⁵ Simon S K Lam, 'SERVQUAL: A tool for measuring patients' opinions of hospital service quality in Hong Kong' (1997) 8(4) *Total Quality Management* 145, 151-152.

monitoring system, the quality of health care would not be properly evaluated, and health practitioners would not be made publicly accountable for service quality.¹⁴³⁶ Telemedicine may improve the existing inequitable access to health care in China,¹⁴³⁷ especially for people living in rural areas, enhance the quality of healthcare services,¹⁴³⁸ and help to rectify the misdistribution of resources.¹⁴³⁹

8.3 Developments in Telemedicine in Hong Kong and China

Hong Kong and China conducted the first cross-border telemedicine project through teleconference in 1996.¹⁴⁴⁰ Hong Kong has been developing telemedicine applications since the 1990s¹⁴⁴¹ and most telehealth applications provide specialized services instead of primary care.¹⁴⁴² Although Hong Kong is a small city and has a high standard of living, Au and colleagues have identified five major reasons why telemedicine is still required in Hong Kong: geographical conditions, high cost of living, insufficient medical resources in the public sector, lack of medical expertise in certain specialties, and improving the efficiency and quality of accident and emergency services.¹⁴⁴³ For example, a safe inter-hospital transfer is crucial in neurosurgical emergencies. Poon and Goh found that teleradiology improves patient management by offering higher clinical diagnostic accuracy and preventing secondary insults when head-injured and unconscious patients are transferred from a general hospital to a neurosurgical unit of another hospital in Hong Kong.¹⁴⁴⁴ Wootton said that Hong Kong would play an important role in the global development of telemedicine especially in research when he noticed that Hong Kong had started the first formal research trial on teleradiology whilst other studies in the world were still largely qualitative.¹⁴⁴⁵

¹⁴³⁶ Ma, Lu and Quan (n 1431) 943.

¹⁴³⁷ Moffatt and Eley (n 135).

¹⁴³⁸ A Garingo, P Friedlich, L Tesoriero, S Patil, P Jackson and I Seri, 'The use of mobile robotic telemedicine technology in the neonatal intensive care unit' (2012) 32 *Journal of Perinatology* 55, 55.

¹⁴³⁹ Thomas R McLean, 'International Law, Telemedicine & Health Insurance: China as a Case Study' (2006) 32(1) *American Journal of Law & Medicine* 7, 17.

¹⁴⁴⁰ Hsieh and others (n 56) 142.

¹⁴⁴¹ Ko (n 57).

¹⁴⁴² Liu Sheng and others (n 41) 252.

¹⁴⁴³ Grace Au, Kunihiro Higa, Ching Kwong Kwok and Andrew Y S Cheng, 'The Development of Telemedicine in Hong Kong' (1996) 6(4) *Journal of Organizational Computing and Electronic Commerce* 365, 370-373.

¹⁴⁴⁴ W S Poon and K Y C Goh, 'The impact of teleradiology on the inter-hospital transfer of neurosurgical patients and their outcome' (1998) 4(3) *Hong Kong Medical Journal* 293.

¹⁴⁴⁵ R Wootton, 'Telemedicine in Hong Kong' (1998) 4(3) *Hong Kong Medical Journal* 259, 260.

In China, the initial use of telemedicine can be traced back to 1986 when the Guangzhou Ocean Shipping Company used telegrams to provide remote diagnoses for its crews, and telemedicine has grown rapidly since the 1990s, especially after the treatment of two Chinese patients with international help through the Internet in 1995.¹⁴⁴⁶ There are some barriers impeding the development of telemedicine in China: legally, the lack of national law hinders the growth of telemedicine; financially, most Chinese people cannot afford the cost of telemedicine and doctors do not have incentives to practise telemedicine services; technically, the telecommunication infrastructure in rural districts in China is insufficient, Chinese hospitals lack qualified IT specialists and knowledgeable senior management to support and advocate the use of telemedicine, and furthermore, there is no national health data standard in China, though international standards such as the Health Level Seven Clinical Document Architecture, DICOM and the Systematized Nomenclature of Medicine (SNOMED) are available; and finally on the people side, Chinese patients prefer face-to-face consultations to remote online consultations, and some of them are not educated and may not even have seen a computer.¹⁴⁴⁷ Despite these barriers, China is devoted to developing telemedicine and has planned to promote telemedicine as a means of enhancing the development of education, health and culture in rural areas.¹⁴⁴⁸ Apart from the three major telemedicine networks established since 1997, namely the Golden Health Network, the International MedioNet of China, and the People's Liberation Army,¹⁴⁴⁹ China has also made use of wireless communication technologies such as Bluetooth and mobile phone transmissions for telehealth applications.¹⁴⁵⁰ The coverage of telemedicine also grows. A recent example includes the development of a telemedicine network covering more than 1,300 Chinese military hospitals to facilitate medical consultations and telemedical training.¹⁴⁵¹

¹⁴⁴⁶ Zhao and others (2010) (n 167) 634-635.

¹⁴⁴⁷ Zhelong Wang and Hong Gu, 'A review of telemedicine in China' (2009) 15(1) *Journal of Telemedicine and Telecare* 23, 25.

¹⁴⁴⁸ China, 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) (n 60) [14].

¹⁴⁴⁹ Zhao and others (2010) (n 167) 635.

¹⁴⁵⁰ Wang and Gu (n 1447) 23-25.

¹⁴⁵¹ 'The official opening of the Telemedicine Centre at the National University of Defense Technology Hospital of the People's Liberation Army General Hospital' *Science & Technology Daily* (5 July 2011) ('解放軍總醫院遠端醫學國防科大醫院網站正式開通' *科技日報* (2011年07月05

8.4 Cross-Border Telemedicine between Hong Kong and China

In telemedicine there are two salient sets of legal issues: (a) issues on whether telemedicine affects the risks of litigation or its outcomes, and (b) safety and efficacy issues on whether there are inherent risks attributable directly to telemedical practices.¹⁴⁵² The first set of legal issues has been addressed in Chapter 4. Health practitioners and institutes in telemedicine may be subject to a higher risk of litigation for clinical negligence,¹⁴⁵³ especially when a claimant cannot realize which health practitioners are liable for the alleged adverse event. As for the issue as to whether telemedicine affects litigation outcomes, the rulings of the Supreme Court of New York in *Bienz v Central Suffolk Hospital*¹⁴⁵⁴ and the Appellate Court of Illinois in *Bovara v St. Francis Hospital*¹⁴⁵⁵ about the establishment of a physician-patient relationship in a patient-doctor telephone call and in an informal consultation between doctors may shed light on this issue. Although these cases were not clinical negligence claims in telemedicine, they have pointed out that it is a question of fact to decide whether a health practitioner or a health institute will be liable. The second set of legal issues concerns patient safety. Patients in telemedical practices may wish to know whether telemedicine will serve them in accordance with prevailing professional norms and practices, whether their safety and right to privacy will be compromised, and which parties will be liable if there is equipment failure or when the equipment fails to provide adequate information, etc.¹⁴⁵⁶ Liability and patients' concerns in cross-border telemedicine between Hong Kong and China are examined below.

8.4.1 Medical Liability

Clinical negligence is one of the areas in telemedicine attracting litigation.¹⁴⁵⁷ In cross-border practices of telemedicine, Hong Kong and China are

曰); 'jiě fāng jūn zǒng yī yuàn yuǎn chéng yī xué guó fāng kē dà yī yuàn zhàn diǎn zhèng shì kāi tōng' kē jì rì bào (2011 nián 7 yuè 5 rì))

<http://big5.xinhuanet.com/gate/big5/news.xinhuanet.com/mil/2011-07/05/c_121623049.htm> accessed 1 February 2012.

¹⁴⁵² Sanders and Bashshur (1995) (n 32) 119-120.

¹⁴⁵³ Kuszler (n 5) 326.

¹⁴⁵⁴ 163 A.D.2d 269, 557 N.Y.S.2d 139 (N.Y.A.D., 1990) (Supreme Court of New York).

¹⁴⁵⁵ 298 Ill.App.3d 1025, 700 N.E.2d 143 (Ill.App. 1 Dist., 1998) (Appellate Court of Illinois).

¹⁴⁵⁶ London (n 1246) 120.

¹⁴⁵⁷ Caryl (n 130) 182.

subject to a new legal impact arising from this state-of-the-art technology, as there are different interpretations of clinical negligence in the common law and in the Chinese civil law. At common law telemedicine challenges the traditional doctrine of clinical negligence in at least three areas: health practitioner-patient relationship, the duty of care arising from the relationship, and the standard of care.¹⁴⁵⁸ The most significant issues for a health practitioner practising telemedicine are whether a health practitioner-patient relationship is established over the cyber environment, whether he or she owes a tele-patient a duty of care, and what standards of care would be applicable in telemedical care.¹⁴⁵⁹ Contrary to the common law, the Chinese HMA Regulation 2002 iterates the violation of the Chinese statutes, regulations, rules and conventions in an adverse medical event.¹⁴⁶⁰

At common law, a claimant in a clinical negligence claim has the onus of proof to show that the defendant health practitioner who owes a duty of care to the claimant has failed to exercise reasonable care, has breached the duty of care and caused the claimant's injury. The claimant is also required to prove that the injury was not too remote.¹⁴⁶¹ As discussed in Chapter 3, the English tort law for clinical negligence claims is relatively uniformly applied across different common law countries. Being a member of the common-law family, Hong Kong also applies the above legal considerations in clinical negligence claims, irrespective of whether it was under the colonial administration of the UK or it is under the unique 'One Country Two Systems' philosophy. Sovereignty over Hong Kong was returned to China in 1997. Under the philosophy of 'One Country Two Systems', the Basic Law of Hong Kong stipulates that the laws previously in force in Hong Kong, i.e. the common law, rules of equity, ordinances, subordinate legislation and customary law are to be maintained, except for those contravening the Basic Law, and subject to any legislative amendments by the Legislative Council of Hong Kong.¹⁴⁶² The Court of Final Appeal in *Bank of East Asia Ltd v Tsien Wui Marble Factory Ltd & Others*¹⁴⁶³ and in *A Solicitor (24/07) v Law Society of Hong Kong*¹⁴⁶⁴ has confirmed that the

¹⁴⁵⁸ Kuszler (n 5) 307.

¹⁴⁵⁹ Fleisher and Datta (n 27) 1-47 §1.04[3].

¹⁴⁶⁰ Yang and Li (n 298) 146.

¹⁴⁶¹ Emily Jackson (n 325) 108.

¹⁴⁶² Hong Kong, The Basic Law of the Hong Kong Special Administrative Region of the People's Republic of China, art 8.

¹⁴⁶³ (1999) 2 HKCFAR 349, 353, [2000] 1 HKLRD 268, 272 (Court of Final Appeal) (Nazareth NPJ).

¹⁴⁶⁴ (2008) 11 HKCFAR 117, [2008] 2 HKLRD 576 (Court of Final Appeal).

common law prior to the changeover continues to apply in Hong Kong after the changeover. The Court of Final Appeal in *Yu Yu Kai v Chan Chi Keung*,¹⁴⁶⁵ for example, endorsed the English approach in the area of tort in 2009, whereas in the area of professional misconduct in particular, the Court of Appeal referred to the *Bolam*¹⁴⁶⁶ principle and *Sidaway v Bethlem Royal Hospital*¹⁴⁶⁷ in a recent case, *Dr Leung Shu Piu v The Medical Council of Hong Kong*.¹⁴⁶⁸

In China, how its medical negligence disputes were resolved was rarely known to outsiders or they were not interested in it. Following the State Council's issuance of the *Opinions on Further Encouragement and Guidance of Private Investment in the Establishment of Medical Institutions*¹⁴⁶⁹ in December 2010 to encourage foreign investments in the provision of health care services in China, how the Chinese clinical negligence system works may become an area of interest to foreigners.¹⁴⁷⁰ Chapter 3 briefly introduced the two 'medical liability regimes' in China after the enactment of the Chinese Tort Law 2010,¹⁴⁷¹ where the judicial regime runs the Chinese Tort Law 2010 to deal with non-medical-accident negligence and the administrative regime runs the Chinese HMA Regulation 2002 to deal with statutorily defined 'medical accidents'.¹⁴⁷² The General Principles of the Civil Law of China provides that when people have fault, encroach on the property of the state, the public or other people, or harm other persons, they may bear civil liability.¹⁴⁷³ In the judicial regime, the newly enacted Chinese Tort Law 2010 pinpoints that if a health institute or its medical employee is at fault and makes a patient suffer from any harm during diagnosis and treatment, the health institute assumes compensatory liability.¹⁴⁷⁴ A health institute will not be responsible for compensatory liability for any harm caused to a patient if its medical staff have fulfilled the duty of reasonable

¹⁴⁶⁵ (2009) 12 HKCFAR 705, [2009] HKEC 328 (Court of Final Appeal).

¹⁴⁶⁶ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

¹⁴⁶⁷ [1985] AC 871, [1985] 1 All ER 643 (House of Lords).

¹⁴⁶⁸ [2011] HKEC 348 (Court of Appeal).

¹⁴⁶⁹ China, Office of State Council, *Opinions on Further Encouragement and Guidance of Private Investment in the Establishment of Medical Institutions* (No. [2010] 58, 26 November 2010) ('國務院辦公廳，關於進一步鼓勵和引導社會資本舉辦醫療機構的意見 (2010 年 11 月 26 日，國辦發 [2010] 58 號)'; *guó wù yuàn bàn gōng tīng, guān yú jìn yī bù gǔ lì hé yǐn dǎo shè huì zī běn jǔ bàn yī liáo jī gòu de yì jiàn (2010 nián 11 yuè 26 rì, guó bàn fā [2010] 58 hào)*).

¹⁴⁷⁰ Xi and Yang (n 355) 65.

¹⁴⁷¹ Ibid 65-66.

¹⁴⁷² Ibid 68.

¹⁴⁷³ General Principles of the Civil Law of the People's Republic of China (中華人民共和國民法通則; *zhōng huá rén mín gòng hé guó mín fǎ tōng zé*), art 106.

¹⁴⁷⁴ Tort Law of the People's Republic of China (中華人民共和國侵權責任法; *zhōng huá rén mín gòng hé guó qīn quán zé rèn fǎ*) 2010, art 54.

diagnosis and treatment in emergency cases¹⁴⁷⁵ or the diagnosis and treatment of the patient is difficult due to the medical knowledge at the time,¹⁴⁷⁶ but it should assume compensatory liability when its employees fail to fulfill the obligations of diagnosis and treatment up to the prevalent standard of care at the material time and cause any harm to a patient.¹⁴⁷⁷ In the administrative regime, details of handling medical malpractice cases are governed by the Chinese HMA Regulation 2002. Article 2 of the 2002 Regulation defines ‘medical accident’¹⁴⁷⁸ as one that has caused personal injury to a patient negligently by a medical institution or the staff thereof in the activities of medical treatment which have violated ‘the laws, regulations, ministerial rules concerning medical treatment and health, or the standards or conventions of medical treatment and nursing’.¹⁴⁷⁹ For a clinical negligence claim to succeed, four elements have to be in existence:¹⁴⁸⁰ a tortious act,¹⁴⁸¹ the defendant’s fault,¹⁴⁸² the damage,¹⁴⁸³ and the causal relationship between the damage and the alleged tortious act.¹⁴⁸⁴ Any damage not meeting the stipulated legal standards and requirements will not make an event become a medical incident.¹⁴⁸⁵

8.4.1.1 Health Practitioner-Patient Relationship and the Duty of Care

The different understanding of the health practitioner-patient relationship in the respective jurisdictions of a cross-border telemedical practice may affect the legal parameters of the relationship.¹⁴⁸⁶ The common law considerations on the establishment of a legal relationship between health practitioners and patients have been discussed in detail in Chapter 4. In brief, it is anticipated that in a clinical negligence claim in a telemedicine setting, a common-law court may examine parties’

¹⁴⁷⁵ Ibid art 60(2).

¹⁴⁷⁶ Ibid art 60(3).

¹⁴⁷⁷ Ibid art 57.

¹⁴⁷⁸ ‘醫療事故’ (*yī liáo shì gù*) in Chinese.

¹⁴⁷⁹ ‘醫療衛生管理法律、行政法規、部門規章和診療護理規範、常規’ (*yī liáo wèi shēng guǎn lǐ fǎ lǜ、xíng zhèng fǎ guī、bù mén guī zhāng hé zhěn liáo hù lǐ guī fàn、cháng guī*) in Chinese.

¹⁴⁸⁰ Yinghai Long and Yabin Li (eds), *Judges Tell You* (Jilin People’s Publishing House, Changchun Municipal, China 2005) (龍英海及李亞斌(主編), 法官告訴您怎樣打醫療糾紛官司(吉林人民出版社, 中國長春市 2005); long yīng hǎi jí lǐ yà bīn (*zhǔ biān*) fǎ guān gào sù nín zěn yang dǎ yī liáo jiū fēn guān sī (*jī lín rén mín chū bǎn shè、zhōng guó cháng chūn shì* 2005)) 89.

¹⁴⁸¹ ‘侵權行為’ (*qīn quán xíng wéi*) in Chinese.

¹⁴⁸² ‘被告過錯’ (*bèi gào guò cuò*) in Chinese.

¹⁴⁸³ ‘損害後果’ (*sǔn hài hòu guǒ*) in Chinese.

¹⁴⁸⁴ ‘醫療行為與損害結果之間的因果關係’ (*yī liáo xíng wéi yǔ sǔn hài jié guǒ zhī jiān de yīn guǒ guān xì*) in Chinese.

¹⁴⁸⁵ Zhao and Zhang (2011) (n 360) 74.

¹⁴⁸⁶ Kluge (n 1080) e2.

conduct in a telemedicine encounter, for example, whether a health practitioner agreed to see a patient online, whether the contents of telemedical communications were relevant to clinical diagnosis of the patient's health conditions, whether the patient relied on the practitioner's advice,¹⁴⁸⁷ whether actual examinations were carried out, whether the practitioner could access the patient claimant's medical records, and whether the practitioner accepted a consultation fee¹⁴⁸⁸ to decide whether a health practitioner-patient relationship in a telemedical application was established. Also, telemedicine may effectively increase the likelihood of imposing a legal duty of care on an advising health practitioner, as a patient, a treating health practitioner and an advising specialist in a telemedical consultation, for example, may see each other through the use of telemedical devices and the patient may give consent online to any examination, diagnosis and treatment.¹⁴⁸⁹

In China, the issues of legal relationship between a health practitioner and a patient and the practitioner's duty of care in the context of telemedicine are seldom covered in literature. There is no law governing these two tele-issues, either. In general, there are three types of health practitioner-patient relationship: contractual relationship, 'management without cause' relationship¹⁴⁹⁰ and mandatory medical relationship in China.¹⁴⁹¹ The first contractual relationship is formed when a patient goes to a health institute and requests a medical registration as an offer and the health institute gives the patient a registration note as an acceptance. The health institute cannot refuse the contractual acceptance as many Chinese laws have stipulated the protection of basic rights of citizens, in particular article 98 of the General Principles of the Civil Law, which states that people in China have the right to health and life. Health institutes have a duty to treat in this regard.¹⁴⁹² Whether health institutes providing telemedicine still assume this somewhat mandatory contractual duty for tele-patients is unclear. The establishment of the second relationship is made out of no cause or no contractual offer. The usual examples are voluntary medical services out of consideration of humanity. The third one is established in accordance with the

¹⁴⁸⁷ Kuszler (n 5) 310.

¹⁴⁸⁸ Fleisher and Datta (n 27) 1-48 §1.04[3].

¹⁴⁸⁹ Caryl (n 130) 194.

¹⁴⁹⁰ '無因管理關係' (*wú yīn guǎn lǐ guān xì*) in Chinese.

¹⁴⁹¹ '強制醫療關係' (*qiáng zhì yī liáo guān xì*) in Chinese.

¹⁴⁹² Xuemei Hou, *Patients' Right – Concepts and Practical Guide* (Intellectual Property Publishing House, Beijing, China 2005) (侯雪梅, *患者的權利 – 理論探微與實務指南* (智慧財產權出版社, 中國北京 2005); *hóu xuě méi, huàn zhě de quán lì – lǐ lùn tàn wēi yǔ shí wù zhǐ nán* (*zhī shì chǎn quán chū bǎn shè, zhōng guó běi jīng* 2005)) 13-14.

law for patients such as drug addicts and mental patients.¹⁴⁹³ The Central Committee of the Chinese Communist Party and State Council promulgated its plan to ‘build a sound and harmonious physician-patient relationship’ in March 2009.¹⁴⁹⁴

Unlike other jurisdictions such as Oklahoma in the US and Malaysia, there is no legislation in Hong Kong or China to help ascertain liability arising from telemedicine. In Hong Kong, legal puzzles such as when an alleged doctor-patient relationship is established over the Internet, whether informal consultations between health practitioners will impose a legal duty of care on consulting practitioners in a telemedical encounter, and which health practitioners in a multi-party telemedical service are liable for a patient’s injury have to be subject to existing case law and other legislation available in Hong Kong when a real telemedical clinical negligence claim comes before the court. In fact, the number of cases in the area of medical negligence in telemedicine is rare worldwide, if not none, despite Stanberry’s anticipation made in 1997 that ‘[it] is simply a matter of time’ for the first or a major claim to arrive.¹⁴⁹⁵ In China, as mentioned before, there is little scholarly literature discussing how Chinese law will impact on telemedicine. In the absence of specific law and regulations and with a lack of sufficient legal discussion in respect to telemedicine, it is not clear whether the Chinese version of the health practitioner-patient relationship and the duty of care will be affected or not, in addition to the fact that the former will be subject to changes as promulgated by the Central Committee of the Chinese Communist Party and State Council in 2009.

8.4.1.1.1 Uncertainty of Time of the Establishment of Health Practitioner-Patient Relationship in Telemedicine

As for the general concern about the uncertainty as to when a health practitioner-patient relationship will be established in telemedicine, especially in the ‘store-and-forward’ mode, it seems it is not a real concern for the cross-border telemedical practices between Hong Kong and China, as both the Electronic

¹⁴⁹³ Qingsheng Li and Jiaju Tan (eds), *Legal Risk of Hospitals: Practical Processing Guidance of Medical Malpractice* (Law Press China, Beijing, China 2004) (李慶生及譚家駒 (主編), *醫院的法律風險：醫療事故法律責任處理實用指南* (法律出版社, 中國北京 2004); *lǐ qīng sheng jí tán jiā jū (zhǔ biān) yī yuàn de fǎ lǚ fēng xiǎn : yī liáo shì gù fǎ lǚ zé rèn chǔ lǐ shí yòng zhǐ nán (fǎ lǚ chū bǎn shè · zhōng guó běi jīng 2004)*) 51.

¹⁴⁹⁴ China, Central Committee of the Chinese Communist Party and State Council, *Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System* (No. [2009] 6, 17 March 2009) (n 482) [13].

¹⁴⁹⁵ Benedict A Stanberry (n 568) 54 [7.2].

Transactions Ordinance¹⁴⁹⁶ of Hong Kong and the Law of the People's Republic of China on Electronic Signature¹⁴⁹⁷ contain provisions governing the time of sending and receipt of an electronic record. In Hong Kong, section 19 of the Ordinance spells out that unless otherwise agreed between the sender and the recipient of an electronic record, the time of sending an electronic record is determined by when it is accepted by an information system outside the control of the sender.¹⁴⁹⁸ The time of receipt is determined by whether the recipient has designated an information system to receive the electronic record or not. If an information system is designated, receipt occurs at the time when the electronic record is accepted by the designated information system.¹⁴⁹⁹ If the electronic record is sent to an information system other than the designated information system¹⁵⁰⁰ or if there is no such designated system,¹⁵⁰¹ receipt occurs when the electronic record comes to the knowledge of the addressee. Similarly, article 11 of the Law of the People's Republic of China on Electronic Signature states that the time of sending out an electronic message is deemed to be the time when the message enters an information system beyond the control of the sender. Receipt occurs at the time when the designated information system receives the electronic message or at the first time the message enters any information system of the recipient if there is no designated information system. If the parties concerned have agreed otherwise on the time of dispatch or the time of receipt of data messages, such agreement shall be complied with.

Theoretically, when there is no designated information system, there is still a statutory difference in the time of receipt between the Hong Kong statute and the Chinese law. According to the Hong Kong law, receipt occurs when the electronic record comes to the knowledge of the addressee; and in China, receipt occurs at the first time when the message enters a non-designated information system of the recipient. In practice, the existence of the Electronic Transactions Ordinance and the Law of the People's Republic of China on Electronic Signature has cleared up to a certain extent the previous uncertainty of time in establishing a legal relationship between a health practitioner and a patient in the cyber environment. If parties have

¹⁴⁹⁶ Section 19.

¹⁴⁹⁷ ‘中華人民共和國電子簽名法’ (*zhōng huá rén mín gòng hé guó diàn zǐ qiān míng fǎ*), art 11.

¹⁴⁹⁸ Section 19(1).

¹⁴⁹⁹ Section 19(2)(a)(i).

¹⁵⁰⁰ Section 19(2)(a)(ii).

¹⁵⁰¹ Section 19(2)(b).

agreed in advance the time of dispatch and receipt or have chosen a particular jurisdiction as the governing law, a further higher degree of certainty is expected.

As regards the real-time mode of telemedical consultations, in Hong Kong, section 17 of the Electronic Transactions Ordinance does not expressly enact when an electronic contract will be concluded but has spelt out that a contract should not be denied validity or enforcement on the sole ground that an electronic record was used in the contract formation and that this section does not affect any rule of common law to the effect that the offeror may prescribe the method of communicating acceptance. At common law, making an analogy to Denning LJ's statement given in the Court of Appeal in *Entores Ltd v Miles Far East Corp*¹⁵⁰² about telex message, express and instantaneous contracts in telemedicine through health-related websites and/or real-time consultations may likely be formed when details such as the nature of the telemedical services, requirements for patients' informed consent, express disclaimers and waivers of liability, etc. are shown to potential patients online.¹⁵⁰³ Also, this submission has further been supported by case law in the US involving telephone consultations that a physician-patient relationship is likely to be established in situations where a doctor sees a patient during a telemedicine visit, where actual examinations have been performed, where the patient relies on diagnosis, treatment and other care, where the doctor has access to the patient's medical records, and where the doctor accepts a fee for the telemedical consultation.¹⁵⁰⁴ For telemedicine involving the use of emails, the Australian case, *Olivaylle Pty Ltd v Flottweg GMBH & Co KGAA (No 4)*,¹⁵⁰⁵ provides a recent legal reference that an online contract may be made where the acceptance is received.

In China, the formation of an electronic contract is governed by the Contract Law of the People's Republic of China.¹⁵⁰⁶ Its article 16 requires that a contractual offer becomes effective when it reaches the offeree. If a contract is concluded electronically and a recipient has designated a specific system to receive digital messages, the time when a digital message enters that specific system is the time of arrival. If there is no specific system designated, the time when the digital

¹⁵⁰² [1955] 2 QB 327, 337, [1955] 2 All ER 493 (Court of Appeal).

¹⁵⁰³ Blum (n 67) 438.

¹⁵⁰⁴ Fleisher and Datta (n 27) 1-48 §1.04[3].

¹⁵⁰⁵ [2009] FCA 522, (2009) 255 ALR 632 (Federal Court of Australia).

¹⁵⁰⁶ Contract Law of the People's Republic of China (中華人民共和國合同法; *zhōng huá rén mín gòng hé guó hé tóng fǎ*).

message first enters any of the recipient's systems will be regarded as the time of arrival. Article 26 states that a contractual acceptance becomes effective when it reaches the offeror. In electronic transmissions, the time of arrival of the digital acceptance is governed by the same rules as are stipulated in article 16. As real-time consultations are instantaneous, contracts may also likely be formed when details of the telemedical services including informed consent, express disclaimers and waivers of liability, etc. are shown to and accepted by patients in China.

8.4.1.2 Standard of Care

Hong Kong and China assess the reasonableness of the standard of care and causation in different ways. Being a common law city, Hong Kong will likely continue to refer to the *Bolam*¹⁵⁰⁷ principle as modified by *Bolitho*¹⁵⁰⁸ to assess whether the standard of care of a defendant health practitioner was reasonable, and continue to consider issues of causation such as the 'but for' test, other 'robust and pragmatic' approaches, loss of chance, material contribution, remoteness and the doctrine of *novus actus interveniens*, etc. In the context of telemedicine, *Shakoor v Situ*¹⁵⁰⁹ in the UK held that a person practising alternative medicine could not be judged by the standards of health professionals who practised in an equivalent position in orthodox western medicine. A health practitioner practising telemedicine may be subject to a higher standard of care than a practitioner in orthodox western medicine, as he or she cannot have physical contact with a patient in the virtual environment which may have actually limited a practitioner's practices in some circumstances.¹⁵¹⁰ Also, to follow *Bolam*,¹⁵¹¹ computer skills may be considered special skills in court for a health practitioner who has held himself or herself out as a telemedicine specialist. However, in a case similar to *Shakoor v Situ*, the lower court in Hong Kong has adopted an interesting approach. In *Tai Kut Sing v Choi Chun Kwan*,¹⁵¹² the defendant held himself out to be a practitioner in Chinese medicine in Hong Kong, specializing in the treatment of haemorrhoids. The claimant suffered injury after the defendant treated him for his haemorrhoids. Glofcheski criticized that in *Tai Kut Sing*, the trial judge gave his ruling without citation of case law, without

¹⁵⁰⁷ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

¹⁵⁰⁸ [1998] AC 232, [1997] 4 All ER 771 (House of Lords).

¹⁵⁰⁹ [2001] 1 WLR 410, [2000] 4 All ER 181 (High Court Queen's Bench).

¹⁵¹⁰ Magenau (n 499) 33.

¹⁵¹¹ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen's Bench).

¹⁵¹² HCPI000812/1995 (Court of First Instance).

explanation as to what the reasonable standard of care of a herbalist like the defendant who specialized in ‘curing haemorrhoids’ should be, and even without making reference to western medical literature as pointed out in *Shakoor*.¹⁵¹³ Telemedicine is still an emerging area not only in medicine but also in law, if a trial court were to make use of the same approach in *Tai Kut Sing* to hear a negligence claim relating to telemedical practices, the reliability and transparency of the legal system in Hong Kong would likely be subject to serious challenges.

In Hong Kong, in addition to the common law standard, statutory standards such as the Code of Practice promulgated by the Director of Health under the Medical Clinics Ordinance¹⁵¹⁴ (Cap 343), which covers registration, employment of staff, accommodation and equipment, medical record keeping, patients’ care and rights, drug records and dispensing, infection control and complaint handling procedures,¹⁵¹⁵ may help determine the standard of care in a clinical negligence claim. However, it is worth noting that compliance with statutory standards does not necessarily mean the standard of care provided was reasonable, and likewise, breach of statutory standards is not always conclusive of negligence. The court will take into account all the circumstances before making a conclusion.¹⁵¹⁶ For example, in the car accident in *Chan Hoi Shan v Chan Man Hing*,¹⁵¹⁷ although the defendant was driving within the statutory limit, his knocking down of a girl was found contributorily negligent as he knew that there was a school nearby and, as an experienced driver, he should have kept a better lookout. In another traffic accident case, *Chan Mei Yee & Others v Ng Tat Cheung*,¹⁵¹⁸ the trial judge accepted the submission of the defendant’s counsel that driving at a speed over the statutory limit did not of itself constitute negligent driving.

In China, the Chinese HMA Regulation 2002 requires the appointment of a society of medical sciences to provide *technical authentication* (professional assessment) of a medical negligence claim either at a local level, a provincial level, or

¹⁵¹³ Glofcheski (n 832) 54-55.

¹⁵¹⁴ Cap 343.

¹⁵¹⁵ Hong Kong, Department of Health, *Code of Practice For Clinics Registered Under The Medical Clinics Ordinance (Cap. 343)* (January 2010) 3.

¹⁵¹⁶ Glofcheski (n 832) 55.

¹⁵¹⁷ HCPI 199/2005 (Court of First Instance) (Sakhrani J).

¹⁵¹⁸ [1992] HKEC 23, HCA004435/1990 (Supreme Court of Hong Kong; renamed High Court in 1997) (Mayo J).

the national level.¹⁵¹⁹ After assessment of a claim based on its facts and ‘irrefutable evidences by making comprehensive analysis of the ... illness of the patient concerned and the differences between ... individuals’,¹⁵²⁰ the experts appointed by a society of medical sciences to provide the technical authentication for the claim under the Regulation have to produce a letter of authentication of medical accidents, the production of which is subject to a majority rule (over 50%).¹⁵²¹ In the letter of authentication, the experts have to conclude, among other things, whether the medical treatment has violated any laws, regulations, ministerial rules concerning medical treatment and health, or any standards or conventions of medical treatment and nursing, and whether there is a causal relationship between the alleged negligent medical act and the patient injury.¹⁵²²

The approaches to assessing the standard of care in Hong Kong and China are not the same. In common law jurisdictions, the principle of *Bolam*¹⁵²³ as modified by *Bolitho*¹⁵²⁴ is commonly considered in clinical negligence cases to determine whether the defendant’s standard of care is reasonable and the parties to such a claim may at least predict their chance of success. In accordance with the principle laid down in *Bolam*, a health practitioner is not guilty of negligence if his or her act or omission is in accordance with a practice accepted as proper by a responsible body of medical experts skilled in that particular form of treatment; nor is the practitioner negligent merely because there is a body of opinion which would adopt a different technique. The House of Lords in *Bolitho* further ruled that when applying the *Bolam* test, the court has to be satisfied that the experts’ opinion as a reference to the defendant doctor’s standard of care should be ‘responsible, reasonable and respectable’ and was capable of withstanding logical analysis, and the experts had ‘directed their minds to the question of comparative risks and benefits’ and reached a defensible conclusion.¹⁵²⁵ A substantial number of ‘responsible medical experts’ is not required for the court to consider whether the practice is reasonable under the *Bolam* principle as modified by *Bolitho*. In *De Freitas v*

¹⁵¹⁹ Regulation on the Handling of Medical Accidents of People’s Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 20.

¹⁵²⁰ *Ibid* art 31.

¹⁵²¹ *Ibid*.

¹⁵²² *Ibid* art 31.

¹⁵²³ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen’s Bench).

¹⁵²⁴ [1998] AC 232, [1997] 4 All ER 771 (House of Lords).

¹⁵²⁵ *Ibid* [1998] AC 232, 242 (Lord Browne-Wilkinson).

O'Brian,¹⁵²⁶ the English Court of Appeal held that although the number of specialist doctors supporting the defendant's position was small (11 versus over 1,000), they were still considered a body of responsible doctors.

In China, as opposed to *Bolam* and *Bolitho* at common law, the over-50% majority rule in the technical authentication as required in the Chinese HMA Regulation 2002¹⁵²⁷ for an expert panel to determine whether a defendant health practitioner's standard of care is in violation of any medical laws, rules and regulations is fundamentally different from what has been practised in Hong Kong. The criteria for assessing the standard of care are not spelt out in both the Chinese HMA Regulation 2002¹⁵²⁸ and the Chinese Tort Law 2010. The criteria for how to determine the causal relationship between a health practitioner's act or omission and a patient's injury are also silent. Expert panels working in such a manner not only put parties to a medical negligence case in a black-box situation similar to what the Chief Medical Officer for England has described, '[It is] a lottery who can and who cannot prove "negligence",'¹⁵²⁹ but also generate unnecessary potential risks and systemic loopholes for misbehaviour within the panels. Yang and Li have pointed out a risk that as the Chinese government does not subsidize the running of these societies of medical sciences, members of the societies are susceptible to any financial incentives, which may affect their impartiality and accountability in the process of making the professional assessment.¹⁵³⁰ To tackle the above black-box concerns, Zhu has proposed a concept similar to the community and national standards of the US that considerations on the standard of care should be given to timing, the differences in locality, sizes of health institutes, standards and knowledge of medical staff in the concerned local districts, and whether it was under emergency, etc.¹⁵³¹ Wang suggested that the standard of technical authentication for medical negligence claims in China should follow a few principles which are similar to the concept of medical negligence at common law tort: professional judgement, the duty of care, whether the

¹⁵²⁶ [1995] PIQR P281, [1995] 6 Med LR 108 (Court of Appeal).

¹⁵²⁷ Art 31.

¹⁵²⁸ Dong Zhu, 'On the Recognition of Medical Standard as the Criterion of Medical Negligence – Experience and Reference from US and Japan' (2011) 9(2) Journal of Liaoning Medical University 17 (朱冬, '作為醫療過失判斷標準的“醫療水平”認定' (2011) 9(2) 遼寧醫學院學報 17; *zhū dōng*, 'zuò wéi yī liáo guò shī pàn duàn biāo zhǔn de “yī liáo shuǐ píng” rèn dìng' (2011) 9(2) *liáo níng yī xué yuàn xué bào* 17), 17.

¹⁵²⁹ United Kingdom, Chief Medical Officer (n 230) 110 [5].

¹⁵³⁰ Yang and Li (n 298) 146.

¹⁵³¹ Zhu (n 1528) 19.

medical treatment in question has met with the appropriate medical standards at the time, informed consent and informed choice, etc.¹⁵³² Ling and Liu have also recognized the great variances of medical standards in villages and cities of China and advocated the use of different standards such as standards of villages against cities and standards of general practitioners against specialists to assess whether a defendant doctor has to bear criminal liability in an alleged medical incident.¹⁵³³

Another concern about assessing the standard of care in a clinical negligence claim involving telemedicine in China is the unavailability of sufficient experts to sit in the expert panels responsible for technical authentications. In 2001, Hsieh and colleagues reported a shortage of trained technical and managerial staff in most medical universities and hospitals providing telemedicine services in China.¹⁵³⁴ It seems the situation has not improved over the years. Almost after a decade, Wang and Gu pointed out in 2009 similarly that hospitals in China lack qualified IT specialists and knowledgeable senior management to support and advocate the use of telemedicine.¹⁵³⁵ In this connection, there is a worry that when an alleged medical negligence claim arises from a telemedical practice, irrespective of whether it is delivered within the same Chinese province, across provinces or cross borders, there may not be a sufficient number of telemedicine experts to sit in an expert panel established under the Chinese HMA Regulation 2002 to make professional assessment about the standard of care and causation in the claim. It is also doubtful what criteria the panel may use to judge the issues of standard of care and causation in a cyber event, in view of the lack of sufficient legal discussion and debates on telemedicine in the Chinese society, not to mention the black-box worries in the process of technical authentication as mentioned before.

¹⁵³² Xu Wang, 'The Basic Principles on Judging Medical Negligence' (2010) 18(4) Evidence Science 434 (王旭, '醫療過失鑒定需遵循的原則' (2010) 18(4) 證據科學 434; wáng xù, 'yī liáo guò shī jiàn dìng xū zūn xún de yuán zé' (2010) 18(4) zhèng jù kē xué 434).

¹⁵³³ Ruijin Ling and Wei Liu, 'Study on the Criminal Liability of Medical Incidents' (2011) 32(6) Journal of Jiangxi University of Science and Technology 33 (凌瑞金及劉瑋, '醫療事故罪的主觀責任要件研究' (2011) 32(6) 江西理工大學學報 33; líng ruì jīn jí liú wěi, 'yī liáo shì gù zuì de zhǔ guān zé rèn yào jiàn yán jiū' (2011) 32(6) jiāng xī lǐ gōng dà xué xué bào 33), 34-35.

¹⁵³⁴ Hsieh and others (n 56) 143.

¹⁵³⁵ Wang and Gu (n 1447) 25.

8.4.1.2.1 Standard of Care in Hong Kong-China Cross-border Telemedicine

In cross-border telemedicine, which jurisdiction's standard of care will prevail over the other is a concern.¹⁵³⁶ As discussed in the preceding section, there are different legal interpretations of what constitutes a reasonable standard of care in Hong Kong and China. Which standard of care, the common law standard or the Chinese one, should apply in a telemedicine application across the borders of Hong Kong and China? Or, is a health practitioner practising this application subject to a higher standard of care¹⁵³⁷ than those prevalent in Hong Kong or China, as his or her practice has been limited by the fact that there is no physical contact between a patient and the health practitioner in the virtual environment? A common view is that the standard of care of the jurisdiction where a patient is located should prevail. In the US, state laws where a patient or a telemedicine health practitioner resides could control an action, unless federal law has pre-empted any state law.¹⁵³⁸ The Federation of State Medical Boards of the US has advocated regulating clinical services by the use of state regulations where a patient is located,¹⁵³⁹ so as to ensure full protection for the patient by that state. Furthermore, health practitioners have to abide by the standard of care existing in the patient's home state, whether or not they are physically in the concerned state, as the best agency to govern health practitioners' compliance with the standard prevalent in the patient's home state is in the medical board in the state of the patient's residence.¹⁵⁴⁰ Also, to address the issue of licensing in different territories, Gitlin has suggested, inter alia, that the referring doctors bear overall responsibility for the care of telemedicine patients and the advising doctors play a consultancy role to give recommendations only.¹⁵⁴¹ The California statute also defines that the resident physician has ultimate authority over patient diagnosis and treatment.¹⁵⁴² Although Nakayasu and Sato think otherwise that it is not reasonable for the attending doctors to assume full responsibility while leaving the ones in the other end of telemedical services free of any liability and they propose that how to divide responsibility between attending and advising doctors be addressed on a case

¹⁵³⁶ A Le Roux, 'Telemedicine: A South African Legal Perspective' (2008) 2008(1) *Journal of South African Law* 99, 110.

¹⁵³⁷ Magenau (n 499) 33.

¹⁵³⁸ Caryl (n 130) 174.

¹⁵³⁹ Federation of State Medical Boards of the United States (1996) (n 39) 2.

¹⁵⁴⁰ *Ibid* 3.

¹⁵⁴¹ Gitlin (n 704) 169.

¹⁵⁴² United States, California Business and Professions Code §2060.

by case basis,¹⁵⁴³ it is the author's submission that the US approach may be of useful reference for the cross-border telemedicine practice between Hong Kong and China, as it has been practised for years with the community standard and the national standard co-existing in the same country.¹⁵⁴⁴

8.4.1.2.2 Credentialing and Licensing

Licensing provides the first line of assurance for patients and the clinical negligence system the second.¹⁵⁴⁵ Different countries have proposed various measures to deal with the licensing and credentialing issues of health practitioners in telemedicine. In the US, to counteract the different licensing requirements of states, professional entities such as the National Council of State Boards of Nursing¹⁵⁴⁶ have studied a multi-state licensure system to facilitate mutual recognitions.¹⁵⁴⁷ In Japan, Nakajima has urged the Japanese Government to revise the Medical Practitioners' Act to allow foreign doctors to practise in Japan or alternatively if the legislative amendment is found difficult, to make mutual recognition arrangements, so as to encourage the growth of telemedicine.¹⁵⁴⁸ In fact, mutual recognition of qualifications has become common not only in Europe but also in ASEAN countries. Like the EU, ASEAN has already agreed to mutually recognize professional qualifications such as medical licences¹⁵⁴⁹ and nursing qualifications¹⁵⁵⁰ to facilitate mobility of health practitioners within ASEAN.

In the case of Hong Kong and China, the current CEPA has also laid a foundation for mutual recognition of professional qualifications, but it may not be effective enough to facilitate the development of telemedicine. The information as at February 2012 showed that under the CEPA, the so-called promotion of professional exchanges between the territories only allows Hong Kong professionals to take Mainland qualification examinations to obtain professional qualifications in

¹⁵⁴³ Nakayasu and Sato (n 153) 10-11.

¹⁵⁴⁴ Zitter (n 610) 608-619.

¹⁵⁴⁵ Caryl (n 130) 191.

¹⁵⁴⁶ Simpson (n 746).

¹⁵⁴⁷ Oberbroeckling (n 1415) 426.

¹⁵⁴⁸ Nakajima, 'Cross-Border Medical Care and Telemedicine' (2012) (n 139) 54.

¹⁵⁴⁹ ASEAN Mutual Recognition Arrangement on Medical Practitioners.

¹⁵⁵⁰ ASEAN Mutual Recognition Arrangement on Nursing Services.

China.¹⁵⁵¹ In addition to the CEPA, the Ministry of Health and the State Administration of Traditional Chinese Medicine of China promulgated in 2009 ‘the Administrative Measures for Hong Kong and Macao Doctors to Obtain Mainland’s “Medical Practitioner’s Qualification Certificates” through Accreditation’,¹⁵⁵² which enables permanent residents of Hong Kong and Macau with Chinese citizenship as well as holding specialist medical qualifications for at least 5 years before 31 December 2007 to have their professional qualifications in clinical medicine, traditional Chinese medicine and dental medicine assessed and accredited.¹⁵⁵³ This set of administrative measures provides an alternative which may be more promising in terms of facilitating the growth of cross-border telemedicine between the two territories.

8.4.1.3 Other Areas of Concern about Medical Liability

8.4.1.3.1 Differences in Health Practices between Hong Kong and China

Cultural and legal differences between the jurisdictions of a health practitioner and a patient in cross-border telemedicine may have an impact on the implementation and success of such a practice.¹⁵⁵⁴ To build a successful telemedicine service with multiple layers such as cross-border telemedicine, health practitioners need to understand the culture, habits, attitudes and behaviours of patients and the partners at the far end of the electronic practice,¹⁵⁵⁵ in addition to their languages, backgrounds, education, goals and mentalities.¹⁵⁵⁶ This is challenging but an essential step in the process of developing telemedicine. People may have a misperception that health problems are managed in the same way in all countries,¹⁵⁵⁷ but in fact, the practices of health practitioners vary from country to country and even

¹⁵⁵¹ Hong Kong, Hong Kong Government, ‘Measures to help Hong Kong enterprises to explore business opportunities on the Mainland’ (Press Release, 29 February 2012) <<http://www.info.gov.hk/gia/general/201202/29/P201202290454.htm>> accessed 19 May 2012.

¹⁵⁵² China, Administrative Measures for Hong Kong and Macao Doctors to Obtain Mainland’s “Medical Practitioner’s Qualification Certificates” through Accreditation (Health and Medical Policy (2009) No. 33) (‘香港和澳門特別行政區醫師獲得內地醫師資格認定管理辦法’, 衛醫政發 (2009) 33 號; ‘xiāng gǎng hé ào mén tè bié xíng zhèng qū yī shī huò dé nèi dì yī shī zī gé rèn dìng guǎn lǐ bàn fǎ’, wèi yī zhèng fā (2009) 33 hào).

¹⁵⁵³ Ibid ss. 2 and 3.

¹⁵⁵⁴ Kluge (n 1080) e4.

¹⁵⁵⁵ Nevins and Pion (n 1240) 197.

¹⁵⁵⁶ Rifat Latifi, ‘The Do’s and Dont’s’ when You Establish Telemedicine and e-Health (Not Only) in Developing Countries’ in Latifi (ed) (2008) (n 90) 40.

¹⁵⁵⁷ Merrell (2004) (n 1238) 145.

from city to city. Patients' perceived differences in health practices including details of treatment may enhance litigation risks in cross-border telemedicine. When they see some health practices abroad which are not in line with what they know from home, they may query the quality of such practices, may have confusion, and may even build up distrust.¹⁵⁵⁸ Also, health practitioners need to be vigilant about patients' differences, as some patients are more vulnerable than others. For instance, Caryl suggested that a telepsychiatric patient is more vulnerable to inflammation due to improper exposure of his or her medical data than others whose X-ray records are seen by unauthorized persons.¹⁵⁵⁹

8.4.1.3.1.1 Different Terminologies

Different terminologies for the same clinical procedures may pose a potential medical liability risk in cross-border telemedicine. For example, intravenous drip is a common clinical procedure for 'the direct administration of artificial sera (replacing, nutrient and medicated) drop by drop, into a selected vein for such variable periods of time ... as may be required',¹⁵⁶⁰ to rehydrate patients or give them medicine or nutrients to revitalize them, for example. In Hong Kong, citizens traditionally and colloquially call this treatment '吊鹽水' ('hanging salt water' literally; *diào yán shuǐ*) in Chinese, though this Hong Kong term is not medically correct. In Macau, where Cantonese is also a common language like Hong Kong, it is called '吊針' ('hanging needle' literally; *diào zhēn*) in hospitals. In China, where mandarin or Putonghua is the official language, it is referred as '點滴' ('drop by drop'; *diǎn dī*) in common parlance. Documentation of the same diagnosis in different terminologies also poses an additional medico-legal risk, as key patient information input by a practitioner in the EHRs of the consulting health institutes may not catch the eyes of advising practitioners who reside elsewhere, and vice versa.¹⁵⁶¹

8.4.1.3.1.2 Drugs

Prescription of drugs is also a potential area of litigation risks. Apart from different terminologies for clinical procedures, drug names may also be different and

¹⁵⁵⁸ Ibid.

¹⁵⁵⁹ Caryl (n 130) 183.

¹⁵⁶⁰ Rudolph Matas, 'The Continued Intravenous "Drip"' (1924) LXXIX(5) *Annals of Surgery* 643, 643.

¹⁵⁶¹ Vigoda, Dennis and Dougherty (n 1171) 52.

the dosage is not uniform throughout the world.¹⁵⁶² A Google search on the Internet shows that a common fever drug bearing a generic name of *paracetamol* in the UK or *acetaminophen* in the US has 95 brand names in different countries.¹⁵⁶³ Another example is a drug bearing the same name in different countries but with different ingredients to treat different diseases. In the US, *Flomax* is a brand name for tamsulosin to treat enlarged prostates, but in Italy, *Flomax* contains morniflumate as an active ingredient and is an anti-inflammatory drug.¹⁵⁶⁴ The Food and Drug Administration of the US gave a warning to consumers in 2006 and advised them not to fill US prescriptions in foreign countries to avoid receipt of wrong medication due to the potential for confusion with brand names.¹⁵⁶⁵ Drugs therefore create a potential risk of clinical negligence in cross-border telemedicine practice between Hong Kong and China if health practitioners are not vigilant enough over prescriptions.

A further issue is how drugs are prescribed. In the US, some doctors and hospitals took advantage of their ability in the marketplace to induce demand and sell pharmaceutical products and healthcare services to patients, where lay people were not able to judge whether the products and services were prescribed based on medical needs or the profits of the doctors and hospitals.¹⁵⁶⁶ In China, following a drug reform in 1978, the drug distribution network has been changed from a central supply mechanism to a market-oriented system and drug manufacturers make their own plans according to the demand of the market, as far as they conform to the law and government guidelines.¹⁵⁶⁷ Similar to the US, research has also revealed that the commercialization of the Chinese drug markets may influence how doctors prescribe drugs and how health institutes purchase drugs. With reforms in these decades, bonus payments are common in China to encourage productivity gains and improvement in efficiency. In the healthcare settings, bonus payments come from the earned profits. As the Chinese government has not restricted the prices of drugs, together with advertisements or other financial incentives such as sales commission to the

¹⁵⁶² Ibid.

¹⁵⁶³ 'List of paracetamol brand names'

<http://en.wikipedia.org/wiki/List_of_paracetamol_brand_names> accessed 17 June 2012.

¹⁵⁶⁴ Terri L Levien, 'International Drug Name Confusion' (2006) 41(7) *Hospital Pharmacy* 697, 701 and Table 1.

¹⁵⁶⁵ Ibid 698-699.

¹⁵⁶⁶ Roger L Poulsen, 'Some current factors influencing the prescribing and use of psychiatric drugs' (1992) 107(1) *Public Health Reports* 47, 50.

¹⁵⁶⁷ Hengjin Dong, Lennart Bogg, Clas Rehnberg and Vinod Diwan, 'Drug policy in China: pharmaceutical distribution in rural areas' (1999) 48(6) *Social Science & Medicine* 777, 778-779.

prescribers,¹⁵⁶⁸ hospitals in China increase the amount of drugs prescribed and use more expensive drugs to generate profits, so as to earn money for running the hospitals and to pay bonuses to staff.¹⁵⁶⁹ This may increase the risk of litigation as patients in cross-border telemedicine sitting on the other end may not accept this type of more-than-necessary prescription practice as proper.

8.4.1.3.1.3 Languages

Language is another different area. Many surveys such as the one conducted by Knowles and colleagues¹⁵⁷⁰ have pointed out that language is one of the barriers to practising telemedicine. This difference is important in cross-border telemedicine between Hong Kong and China, as there are a countless number of dialects in China, many people from different Chinese provinces do not speak standard mandarin (or Putonghua) and often have trouble understanding each other,¹⁵⁷¹ whereas the mother language of many Chinese people in Hong Kong is Cantonese, not mandarin.

8.4.2 Areas of Liability from the Perspective of Patients

8.4.2.1 Patient Safety

8.4.2.1.1 Informed Consent

At common law, if a health practitioner fails to provide sufficient information or to have a patient's consent before treatment, he or she may be liable for assault and battery as well as negligence. Case law has developed three legal standards to judge whether consent given by a patient is 'informed' consent or not: (a) a provider-centred approach as to what reasonable health practitioners would disclose in similar circumstances, (b) a patient-centred approach requiring practitioners to disclose information that reasonable patients in similar circumstances would want to know before making informed decisions, and (c) a purely subjective individual-based approach where health practitioners disclose information that a particular individual

¹⁵⁶⁸ Ibid 784.

¹⁵⁶⁹ William C L Hsiao, 'The Chinese Health Care System: Lessons for Other Nations' (1995) 41(8) *Social Science and Medicine* 1047, 1051 and 1053.

¹⁵⁷⁰ Knowles and others (n 179) 263.

¹⁵⁷¹ Tim Friesner and Mike Hart, 'A Cultural Analysis of e-Learning for China' (2004) 2(1) *Electronic Journal on e-Learning* 81, 84.

patient would want to know.¹⁵⁷² One of the exceptions to the doctrine of informed consent is therapeutic privilege, where disclosure of the risks of treatment poses ‘a threat detrimental to a patient as to become unfeasible or contraindicated from a medical point of view.’¹⁵⁷³

In relation to informed consent over the Internet, health practitioners have to take care of the different standards of disclosure in various countries. Not to mention the purely subjective approach that a health practitioner has to disclose information for a particular individual patient, the standard of informed consent based on the prevalent patient-centred approach in the US, Australia and Canada is significantly higher than the traditional and paternalistic provider-centred standard as adopted by the English legal system. Courts in Hong Kong may, however, continue to follow the English approach.¹⁵⁷⁴ The Medical Council of Hong Kong in its Code of Professional Practice has followed the English common law principles of informed consent.¹⁵⁷⁵ It spells out that a doctor who has not obtained the consent of a patient but carried out diagnostic procedures and medical treatment is liable to allegations of battery and criminal offence such as wounding and assault occasioning actual bodily harm.¹⁵⁷⁶ After explaining the nature, effect and risks of the proposed treatment and other treatment options including no treatment¹⁵⁷⁷ in clear, simple and consistent language understandable by patients,¹⁵⁷⁸ doctors have to give patients a reasonable time for his or her consideration¹⁵⁷⁹ and should respect patients’ refusal of the proposed investigation and treatment.¹⁵⁸⁰ What patients want to know before making consent is not a criterion in the Code of Professional Practice.

The approach to patient consent in China is not identical to the common law practices. Article 11 of the Chinese HMA Regulation 2002 requires health institutes and practitioners to inform patients ‘truthfully’¹⁵⁸¹ of their medical conditions, treatment plans and clinical risks, etc. and to reply to patients’ enquiries in

¹⁵⁷² Altman, Parmelee and Smyer (n 881) 300.

¹⁵⁷³ *Canterbury v Spence* 464 F.2d 772, 789, 150 U.S.App.D.C. 263, 280 (C.A.D.C., 1972) (United State Court of Appeals for the District of Columbia Circuit) (Robinson CJ).

¹⁵⁷⁴ Glofcheski (n 832) 530.

¹⁵⁷⁵ Medical Council of Hong Kong, *Revised section 2 of the Code of Professional Conduct* (promulgated in Issue No. 18 of the newsletter of the Medical Council in October 2011) <http://www.mchk.org.hk/code_section2.pdf> accessed 10 June 2012.

¹⁵⁷⁶ *Ibid* [2.1].

¹⁵⁷⁷ *Ibid* [2.7].

¹⁵⁷⁸ *Ibid* [2.10.1].

¹⁵⁷⁹ *Ibid* [2.8].

¹⁵⁸⁰ *Ibid* [2.9].

¹⁵⁸¹ ‘如實告知’ (*rú shí gào zhī*) in Chinese.

a timely manner. The same article also provides an exception similar to the therapeutic privilege of common law that they may withhold information to a patient if ‘unfavourable consequences’ may happen to the patient. Contrary to the aforesaid three standards of common law informed consent, the Chinese law is silent on how much information is deemed sufficient and what constitutes ‘truthful’ information, but it expressly spells out timeliness as a legal requirement.

There is also another difference where a patient is not capable of giving consent. The English Court of Appeal in *In Re T (Adult: Refusal of Treatment)*¹⁵⁸² dispelled the misconception that the next of kin has a legal right either to consent or to refuse consent on behalf of a patient. In Hong Kong, the Court of First Instance in *Hospital Authority v C*¹⁵⁸³ followed *In Re T (Adult: Refusal of Treatment)* and held that the next of kin did not have legal authority to decide what should or should not happen to a patient or an unborn child. China adopts a different approach to this issue. The Basic Rules of Making Medical Records effective from 1 March 2010 provide exceptions to the practice of informed consent. When a patient is considered not capable of giving consent, his or her legal representative can give consent on the patient’s behalf; if a patient is too weak, the consent can be given by an authorized person; and in situations where it is not in the best interests to inform a patient of his or her health conditions, a health practitioner should inform the patient’s close relative(s) and ask for their consent.¹⁵⁸⁴

8.4.2.1.2 Electronic Signatures

In addition to the technical incompatibility of electronic signatures in cross-border applications, the UN notices the legal incompatibility owing to different legal requirements in various jurisdictions.¹⁵⁸⁵ This concern may also arise in the Hong Kong-China telemedical practices, but legal incompatibility is unlikely to be found in the context of electronic signatures, as both Hong Kong and China have enacted their own laws based on the UNCITRAL Model Law on Electronic Commerce published

¹⁵⁸² [1992] 3 WLR 782, [1993] Fam 95 (Court of Appeal).

¹⁵⁸³ [2003] 1 HKLRD 507, [2003] HKEC 240 (Court of First Instance).

¹⁵⁸⁴ China, Basic Rules of Making Medical Records (Health and Medical Policy (2010) No. 11) (‘病歷書寫基本規範’, 衛醫政發 (2010) 11 號; ‘bìng lì shū xiě jī běn guī fàn’, wèi yī zhèng fà (2010) 11 hào), section 10.

¹⁵⁸⁵ United Nations, United Nations Commission on International Trade Law, *Promoting confidence in electronic commerce: legal issues on international use of electronic authentication and signature methods* (Vienna 2009) 67 [137].

by the UN in 1996. In Hong Kong, the Electronic Transactions Ordinance differentiates an electronic signature from a digital signature.¹⁵⁸⁶ Section 2 of the Ordinance gives legal definitions of these two terms. An ‘electronic signature’¹⁵⁸⁷ means any letters, characters, numbers or other symbols in digital form attached to or logically associated with an electronic record, and executed or adopted for the purpose of authenticating or approving the electronic record, whereas a ‘digital signature’¹⁵⁸⁸ means an electronic signature generated by the transformation of an electronic record using an asymmetric cryptosystem and a hash function such that a person having the initial untransformed electronic record and the signer’s public key can determine (a) whether the transformation was generated using the private key that corresponds to the signer’s public key; and (b) whether the initial electronic record has been altered since the transformation was generated. In China, the legal liability of an electronic signature is set out in the Law of the People’s Republic of China on Electronic Signature,¹⁵⁸⁹ which came into effect on 1 April 2005. Its article 1 states that the purpose of the law is to regulate acts concerning electronic signatures and provide safeguards for the lawful rights and interests of relevant parties. Article 13 of the Chinese law uses the terminology ‘electronic signature’¹⁵⁹⁰ and ‘reliable electronic signature’¹⁵⁹¹ and the latter is considered equivalent to ‘digital signature’ of the Hong Kong law.¹⁵⁹² It spells out that if an electronic signature concurrently meets the following requirements, it is deemed a reliable electronic signature: data that create an electronic signature exclusively belongs to an electronic signatory, the data are controlled only by the electronic signatory, and any alteration made to the electronic signature, the contents and the format of a data message are detectable.¹⁵⁹³ It also stipulates that there are no rules and regulations to govern whether any parties to a contract should use an electronic signature on a document, but if they do, they cannot deny that a document is not legally valid just because electronic means are used.¹⁵⁹⁴ An electronic signatory who has learnt of any defects in the electronic

¹⁵⁸⁶ Cap 553, section 2.

¹⁵⁸⁷ ‘電子簽署’ (*diàn zǐ qiān shǔ*) in Chinese.

¹⁵⁸⁸ ‘數碼簽署’ (*shù mǎ qiān shǔ*) in Chinese.

¹⁵⁸⁹ ‘中華人民共和國電子簽名法’ (*zhōng huá rén mín gòng hé guó diàn zǐ qiān míng fǎ*) in Chinese.

¹⁵⁹⁰ ‘電子簽名’ (*diàn zǐ qiān míng*) in Chinese.

¹⁵⁹¹ ‘可靠的電子簽名’ (*kě kào de diàn zǐ qiān míng*) in Chinese.

¹⁵⁹² Stephenson and Kwan (n 1390) 384.

¹⁵⁹³ Law of the People’s Republic of China on Electronic Signature, art 13.

¹⁵⁹⁴ Ibid art 3.

signature has to inform all concerned parties in a timely manner, failing which the signatory bears the responsibility for compensation.¹⁵⁹⁵

8.4.2.2 Patient Data Protection

8.4.2.2.1 The Duty of Confidentiality

In Hong Kong, the legal protection of privacy is still emerging. In the Basic Law, there are no specific provisions in relation to protection of privacy and confidentiality of health information, but its articles 28, 29 and 30 prohibit an arbitrary or unlawful search of the body of Hong Kong residents or intrusion into their houses or other premises and provides legal protection to ensure residents' freedom and privacy of communication. The Hong Kong Bill of Rights Ordinance also prohibits arbitrary or unlawful interference with a person's privacy, family, home or correspondence and binds the government and all public authorities.¹⁵⁹⁶ In particular, privacy rules pertaining to personal data are enacted in the Personal Data (Privacy) Ordinance.¹⁵⁹⁷ It deals with the collection, handling and use of personal data and allows a claimant who suffers damage including injury to feelings by reason of a contravention of a privacy requirement under the Ordinance to request compensation from the data user for that damage.¹⁵⁹⁸ In this Ordinance, 'data' is defined as 'any representation of information (including an expression of opinion) in any document and includes a personal identifier.'¹⁵⁹⁹ Its section 18 allows individuals to make a request for checking with a data user who 'either alone or jointly or in common with other persons, controls the collection, holding, processing or use of the data'¹⁶⁰⁰ to see if they hold personal data of which the individual is the data subject.¹⁶⁰¹ If affirmative, the individual may ask for a copy of such data.¹⁶⁰² A data user has 40 days to comply with the statutory requirement upon receipt of an individual's request.¹⁶⁰³ However, it is criticized that the Personal Data (Privacy) Ordinance does not spell out privacy rights in general, does not furnish Hong Kong

¹⁵⁹⁵ Ibid art 27.

¹⁵⁹⁶ Cap 383, section 8 (art 14).

¹⁵⁹⁷ Hong Kong, Personal Data (Privacy) Ordinance (Cap 486).

¹⁵⁹⁸ Ibid section 66.

¹⁵⁹⁹ Ibid section 2.

¹⁶⁰⁰ Ibid.

¹⁶⁰¹ Ibid section 18(1)(a).

¹⁶⁰² Ibid section 18(1)(b).

¹⁶⁰³ Ibid section 19.

people with comprehensive privacy protection, and does not provide redress for those whose privacy has been invaded.¹⁶⁰⁴ In response to the Personal Data (Privacy) Ordinance, the Hospital Authority of Hong Kong has prepared a manual specifically for the management of electronic communications and protection of electronic patient data. It has also published an electronic communication policy, covering electronic communications by means of emails, the Internet, Websites, etc. Staff violating the policy will be subject to disciplinary action.¹⁶⁰⁵ Potential claimants may make a request to the hospitals for medical records under the Ordinance. In the context of telecommunication, the Law Reform Commission of Hong Kong recommended in 1996 that it would be an offence to intercept or interfere with a telecommunication or a transmission by radio in the course of transmission.¹⁶⁰⁶ As there were mixed responses to the recommendations,¹⁶⁰⁷ the Interception of Communications and Surveillance Ordinance¹⁶⁰⁸ was enacted in 2006 only to govern public officers' conduct when they intercept communications and use surveillance devices. Protection against improper interception by private parties is still outstanding.

In China, there is no single law governing personal data protection, either. For instance, article 40 of the Constitution protects people's freedom and privacy of communication except where the needs of state security or criminal investigation have to be met. Article 120 of the General Principles of the Civil Law protects the right of personal names, portraits, reputation or honour against infringement. Article 3 of the Interpretation of the Supreme People's Court on Problems regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts¹⁶⁰⁹ stipulates that the Chinese court should accept cases arising from illegal disclosure or use of a deceased's privacy or infringement upon the privacy by other means against public interests or morality. In 2008, the Beijing Chaoyang District People's Court in

¹⁶⁰⁴ Hong Kong, Legislative Council Panel on Home Affairs, 'Protection of Privacy' (LC Paper No. CB(2)1014/06-07(01)) [4].

¹⁶⁰⁵ Private correspondences dated 14 and 18 January 2008 between the Hospital Authority of Hong Kong and the author.

¹⁶⁰⁶ Hong Kong, the Law Reform Commission of Hong Kong, *Report on Privacy: Regulating the Interception of Communications* (Hong Kong, 1996) [4.4].

¹⁶⁰⁷ Hong Kong, Legislative Council Panel on Home Affairs, 'Protection of Privacy' (n 1604) 4-5.

¹⁶⁰⁸ Cap 589.

¹⁶⁰⁹ China, Interpretation of the Supreme People's Court on Problems regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts (最高人民法院關於確定民事侵權精神損害賠償責任若干問題的解釋; *zuì gāo rén mín fǎ yuàn guān yú què dìng mǐn shì qīn quán jīng shén sǔn hài péi cháng zé rèn ruò gān wèn tí de jiě shì*).

*Wang Fei v Zhang Leyi, Daqi.com and Tianya.com*¹⁶¹⁰ addressed for the first time in China the issues of cyber violence and Chinese citizens' right to privacy. This ruling has called for privacy protection reform from the Ministry of Information Industry.¹⁶¹¹

8.4.2.2.2 Electronic Health Records

In Hong Kong, Leung and colleagues revealed in 2001 that over one third of 897 doctor respondents already employed EHRs for patient records, laboratory reporting and making referrals.¹⁶¹² In fact, the Hospital Authority of Hong Kong, the sole public health provider, has allocated a sum of US\$200 million to develop computerized clinical management systems since 1994 and is in recent years strengthening the system for the free flow of electronic patient data between the public and private healthcare settings.¹⁶¹³ Also, the Hong Kong Government committed a sum of US\$90 million in 2009 to steer the development of a 5-year electronic medical data sharing system for healthcare practitioners in both the public and private sectors.¹⁶¹⁴ However, while the Hospital Authority of Hong Kong has promulgated its policy to manage the protection of electronic patient data in public hospitals, it is not clear how well the private healthcare sector protects electronic health information.

In China, the Ministry of Health also established a steering committee in 2008 to study the standards, policies and guidelines of national electronic health information systems.¹⁶¹⁵ Surveys showed that over 80% of hospitals have been equipped with EHRs.¹⁶¹⁶ The Chinese HMA Regulation 2002 is silent on the protection measures for electronically stored patient data, but it provides general protection of medical records in clinical negligence cases and requires that in any

¹⁶¹⁰ No. 10930 (Beijing Chaoyang District People's Court, 18 December 2008) (北京市朝陽區人民法院審理王菲訴張樂奕侵犯名譽權案; *běi jīng shì cháo yang qū rén mín fǎ yuàn shěn lǐ wáng fēi sù zhāng lè yì qīn fàn míng yù quán àn*) <<http://old.chinacourt.org/html/article/200812/18/336418.shtml>> accessed 30 June 2012.

¹⁶¹¹ Anne S Y Cheung, 'A Study of Cyber-Violence and Internet Service Providers' Liability: Lessons from China' (2009) 18(2) *Pacific Rim Law & Policy Journal* 323, 338.

¹⁶¹² Gabriel M Leung, Janice M Johnston, Lai-Ming Ho, Fung-Kam Wong and Susana Castan Cameo, 'Computerization of clinical practice in Hong Kong' (2001) 62(2) *International Journal of Medical Informatics* 143.

¹⁶¹³ Healthcare Information and Management Systems Society (2008) (n 1164) 90-91.

¹⁶¹⁴ Hong Kong, eHealth Record Office, 'History on eHR Development' <http://www.ehealth.gov.hk/en/development_programme/history.html> accessed 31 May 2012.

¹⁶¹⁵ Liang and others (n 206) 281.

¹⁶¹⁶ *Ibid.*

medical disputes, health institutes must keep the originals or photocopies of the medical records concerned. To be seen as a fair process, the medical records have to be sealed and opened in the presence of both parties to a dispute.¹⁶¹⁷ The Basic Rules of Making Medical Records stipulated in 2010 that the Ministry of Health would make separate rules governing electronic medical records.¹⁶¹⁸

8.4.3 Liability Concerns from the Perspective of Health Institutes

A lengthy discussion has been made in Chapter 7 on the institutional areas of liability. In brief, both health practitioners and institutes face organizational challenges in the delivery of telemedical services. In common law jurisdictions like Hong Kong, health practitioners and institutes need to assess their organizational readiness in the planning stage of provision of telemedicine services and consider safeguards to minimize impact arising from any direct liability and others such as potential vicarious liability and medical liability, licensing and credentialing requirements, legal issues on electronic signatures and online patient consent, patient data protection, and criminal risks, etc. Product liability involving telemedical devices and ISPs is also another organizational concern. In China, health institutes which aim at minimizing the risk of clinical negligence may follow five legal strategies with reference to Chapter 2 of the HMA Regulation 2002:¹⁶¹⁹ (a) health practitioners not to breach their duty of care by following medical laws, regulations, rules, norms and processes, as well as medical ethics,¹⁶²⁰ (b) health institutes not to breach their duty through staff training and requesting health practitioners to follow concerned laws, regulations and medical ethics,¹⁶²¹ (c) health institutes to designate responsible departments and staff to supervise and monitor quality of healthcare services,¹⁶²² (d) health institutes to maintain medical records in conformity with the

¹⁶¹⁷ Art 16.

¹⁶¹⁸ China, Basic Rules of Making Medical Records (Health and Medical Policy (2010) No. 11) (‘病歷書寫基本規範’, 衛醫政發 (2010) 11 號; ‘*bìng lì shū xiě jī běn guī fàn*’, *wèi yī zhèng fà* (2010) 11 *hào*), section 37.

¹⁶¹⁹ Qinghua Huang, ‘Clinical risk management, medical negligence prevention and the law: A review’ (2008) 20(4) *The International Journal of Risk and Safety in Medicine* 185, 191.

¹⁶²⁰ Regulation on the Handling of Medical Accidents of People’s Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 2.

¹⁶²¹ *Ibid* arts 5 & 6.

¹⁶²² *Ibid* art 7.

government requirements,¹⁶²³ and (e) health practitioners to truthfully inform patients about their medical condition, treatment options and relevant clinical risk.¹⁶²⁴

In the practice of cross-border telemedicine between Hong Kong and China, it is advisable for health institutes and practitioners to plan and adopt an effective risk management policy to address institutional concerns including organizational liability, service liability, product liability and contractual liability as discussed in the previous chapter and to ensure that the representation of the telemedicine services will not create unnecessary patient expectations, and that the disclosure of service scope and limitations to patients is full.¹⁶²⁵ While there is a lack of legislation in both jurisdictions, health institutes and practitioners still have to face the reality and address issues in actual practices like whether informal consultations will establish a legal health practitioner-patient relationship in a particular telemedical consultation, which health practitioner(s) are liable in a multiple-party consultation, and how to address the unclear legal requirement of section 11 of the Chinese HMA Regulation 2002 with regard to what constitutes truthful information when health institutes and practitioners inform patients of their medical conditions, treatment plans and clinical risks, etc. For the sake of prudence, health institutes and practitioners may consider making reference to the industry practices not only in Hong Kong or China, but those in developed countries such as the US, so as to protect the best interests of telepatients, the institutes and their staff.

To better manage the risk concerns, the American Medical Association has asked its physicians to take precautions when making communication with patients through emails or faxes, including but not limited to physicians' using email correspondence to establish a patient-physician relationship and their obligations to (a) hold the same ethical responsibilities to their patients in email encounters, (b) present electronic information with professional standards, (c) observe inherent limitations of emails such as potential breaches of privacy and confidentiality, difficulties in validating the identity of the parties and possible delays in responses, and (d) allow patients to have the chance to accept or refuse communication of privileged information through emails, etc.¹⁶²⁶ Tomioka has also suggested some useful tips,¹⁶²⁷

¹⁶²³ Ibid art 8.

¹⁶²⁴ Ibid art 11.

¹⁶²⁵ Oberbroeckling (n 1415) 430.

¹⁶²⁶ American Medical Association, *AMA's Code of Medical Ethics* (n 1067) Opinion 5.026.

¹⁶²⁷ Tomioka (n 154) 27.

for example, seeing a patient for the first time in person instead of through the Internet, making cooperation with a health institute in another district instead of seeing a tele-patient in his or her house, no telemedical service until full explanation including failure of IT equipment and the alternative arrangement has been given and patient consent obtained, according a high priority to patient confidentiality and maintenance of electronic medical records, and reminding patients and their family members that it would be their sole liability if they fail to adhere to health practitioners' instructions given through the Internet. To deal with patients' non-compliance and enhance their involvement in taking care of their own health, Saxton proposed taking a proactive risk management by inserting statements such as 'The following information is very important to your health', 'Please take time to fully and accurately fill out this form', and 'The above information is true and correct to the best of my belief' into discharge instructions, informed consent forms, practice brochures, and healthcare websites, etc. to reduce the chance of medical lawsuits.¹⁶²⁸ Health practitioners or institutes are also advised to establish standard protocols and practices to record details such as the identity of persons giving orders, time and date, and what have been ordered, together with standing operational codes such as making proper copies of fax orders on thermal paper before the records fade over time.¹⁶²⁹ Unification of patients' identification numbers is also a basic issue to facilitate effective telecommunication between health institutes and/or practitioners at both ends of a telemedicine consultation.¹⁶³⁰ To manage the legal uncertainty, it may be a practical solution to protect the interests of health practitioners, health institutes and patients in telemedicine by asking the former two to obtain and maintain an enterprise liability insurance policy.¹⁶³¹ In Hong Kong, the Medical Council of Hong Kong has created guidelines for doctors and alerted them that their use of the Internet to give recommendations should take into account changing patients' expectations as they want to know more about a doctor before attending their surgery and they want to know more about their diseases and treatment options.¹⁶³² If doctors use websites for dissemination of health information, as the contents of the websites are not peer-reviewed and the general public cannot check the accuracy of the information, they

¹⁶²⁸ Saxton (n 1232).

¹⁶²⁹ Quan, 'Medical Records and Confidentiality' (n 1129) 212 [6.10] and 213 [6.15].

¹⁶³⁰ Gitlin (n 704) 166-167.

¹⁶³¹ McLean (2002) (n 716) 205.

¹⁶³² Medical Council of Hong Kong (2000) (n 1069).

should ensure that the relevant health information is adequately tested, a balanced view is given, any new medical discoveries uploaded to the websites are of proven value, and the information is honest, factual and accurate.¹⁶³³

As a further risk management strategy, the impact of the Internet on telemedicine should not be underestimated. Google warned the globe in late May 2012 for the ‘July 9th malware’, which would make users’ computers unable to connect to the Internet suddenly on 9 July 2012, affecting an estimated number of 350,000 users worldwide.¹⁶³⁴ As of this writing, the author does not know whether such disastrous events will occur but this warning does demonstrate the importance of having a robust risk management system to manage health services over the Internet.

8.4.4 Criminal Liability

In Hong Kong, there is no single statute to protect computer safety. Cybercrimes such as interception of telecommunications and computer hacking are governed by a number of statutes,¹⁶³⁵ including the Crimes Ordinance,¹⁶³⁶ the Post Office Ordinance,¹⁶³⁷ the Interception of Communications and Surveillance Ordinance¹⁶³⁸ and the Telecommunications Ordinance.¹⁶³⁹ In China, there are five types of statutory cyber crimes, including those of obstructing internet security operations, obstructing national security and social stability, obstructing the order of the socialist market economy and social control, infringing upon the legitimate rights of persons and property, and other cyber crimes.¹⁶⁴⁰ Cybercrimes are governed by the Criminal Law,¹⁶⁴¹ supported by other legislative interpretations and judicial interpretations made by the court. Article 4(2) of the National People’s Congress

¹⁶³³ Ibid.

¹⁶³⁴ Rob Waugh and Christine Show, “‘Internet blackout’ set for 9 July: FBI to ‘pull plug’ on 350,000 virus-infected machines – cutting off Web for users in U.S. and UK” *Mail Online* (United Kingdom, 26 May 2012) <<http://www.dailymail.co.uk/news/article-2150236/Google-launches-campaign-warn-THOUSANDS-victims-infected-computers-kicked-internet-weeks.html>> accessed 27 May 2012.

¹⁶³⁵ Stephenson and Kwan (n 1390) 100.

¹⁶³⁶ Cap 200.

¹⁶³⁷ Cap 98.

¹⁶³⁸ Cap 589.

¹⁶³⁹ Cap 106.

¹⁶⁴⁰ Jianwen Zhang, *The Current Situation of Cybercrimes in China* (International Centre for Criminal Law Reform and Criminal Justice Policy, Vancouver, Canada 2006) 4.

¹⁶⁴¹ Criminal Law of the People’s Republic of China (中華人民共和國刑法; *zhōng huá rén mín gòng hé guó xíng fǎ*) .

Standing Committee Decision Concerning Safeguarding Internet Safety¹⁶⁴² passed on 28 December 2000 states that any people who illegally intercept, change or delete another person's email or other data information, thus infringing upon that person's freedom of communication, shall have committed a crime and take criminal responsibility in accordance with relevant criminal law provisions. Article 32 of the Law of the People's Republic of China on Electronic Signature stipulates that a person who counterfeits, copies or usurps another person's electronic signature commits a crime, bearing criminal responsibility as well as civil responsibility if others suffer any losses.

8.5 Telemedicine Lawsuits Involving Hong Kong and Other Jurisdictions

8.5.1 Conflict of Laws

Transactions and services involving more than one jurisdiction are not uncommon nowadays. Differences in legal systems between territories have impact on the telemedical delivery of health care. When there is any legal dispute involving more than one jurisdiction, the problems of conflict of laws arise. Conflict of laws is a subject that crosses 'jurisdictional lines by definition and ... the lines of many areas of substantive law.'¹⁶⁴³ In the context of litigation, when a dispute arises across borders, conflict of laws may be involved, which addresses basically four issues: (a) courts' jurisdiction over the dispute, (b) which law governs the dispute, (c) whether a court could refuse to exercise its jurisdiction over the dispute, and (d) enforcement of a court's judgment.¹⁶⁴⁴

8.5.1.1 Jurisdiction

In international law, there are three components embedding in the term 'jurisdiction': jurisdiction to prescribe, adjudicate and enforce.¹⁶⁴⁵ In the Reinstatement of Law (Third) of the Foreign Relations Law of the US, the

¹⁶⁴² China, *the National People's Congress Standing Committee Decision Concerning Safeguarding Internet Safety* (全國人民代表大會常務委員會關於維護互聯網安全的決定; *quán guó rén mín dài biǎo dà huì cháng wù wěi yuán huì guān yú wéi hù hù lián wǎng ān quán de jué dìng*).

¹⁶⁴³ Michael Traynor, 'Conflict of Laws, Comparative Law, and the American Law Institute' (2001) 49(3) *The American Journal of Comparative Law* 391, 403.

¹⁶⁴⁴ Dan Jerker Börje Svantesson, 'Cross-Border Telemedicine: New Area, Same Legal Challenges' (2009) 3(2) *Masaryk University Journal of Law and Technology* 227, 232.

¹⁶⁴⁵ Leila Nadya Sadat, 'Redefining Universal Jurisdiction' (2000-2001) 35(2) *New England Law Review* 241, 245.

‘jurisdiction to prescribe’ deals with the application of a state’s law to the activities, relations, or status of persons; the ‘jurisdiction to adjudicate’ refers to the court’s power to adjudicate with respect to a person or thing; and the ‘jurisdiction to enforce’ concerns a court’s power to compel compliance or punish noncompliance with the laws of a state.¹⁶⁴⁶

In telemedicine, where a health-related website provides online medical advice, for example, the website owner or operator has come into contact with a particular person it is interacting with and that person may not be in the same jurisdiction where the website is located.¹⁶⁴⁷ When a dispute arises, the extent of such ‘contact’ may be considered by court as to whether it will exercise its jurisdiction. In the US, some ‘minimal contacts’ between a state and a person seeking jurisdiction are required for a court in the state to exercise its jurisdiction over the person, and jurisdiction resides in the state where the incident took place or in the patient’s home state in the case of an out-of-state medical consultation.¹⁶⁴⁸ In *International Shoe v State of Washington*, the Supreme Court of the United States held that if a person is not present within the territory of a state, the ‘due process of law’ requires that he has certain minimum contacts with it, so that the ‘traditional notions of fair play and substantial justice’ will be maintained.¹⁶⁴⁹ In *Hageseth v Superior Court*,¹⁶⁵⁰ the defendant doctor who practised telemedicine outside California was charged with felony offence of practising medicine without a licence in California. The defendant appealed based on the ground of lack of jurisdiction. The California Court of Appeal held that the state had jurisdiction over the defendant under traditional principles and it was immaterial to jurisdiction that the alleged offence was committed over the Internet and that the ‘minimum contacts’ test for jurisdiction over an out-of-state defendant may also be extended to criminal cases involving a corporate defendant.

¹⁶⁴⁶ §401(a)-401(c).

¹⁶⁴⁷ Svantesson (n 1644) 229.

¹⁶⁴⁸ Matthew L Howard, ‘Physician-Patient Relationship’ in Sanbar and others (eds) (2004) (n 988) 336.

¹⁶⁴⁹ 326 U.S. 310, 66 S.Ct.154, [3] (U.S. 1945) (Supreme Court of the United States).

¹⁶⁵⁰ 150 Cal.App.4th 1399, 59 Cal.Rptr.3d 385 (Cal.App. 1 Dist., 2007) (California Court of Appeal, First District).

8.5.1.2 Choice of Law

The tortious liability rules of different countries in the context of health care are complex and diverse and it is important to choose an applicable law before running cross-border telemedicine practices.¹⁶⁵¹ From the perspective of contract, the difficulties of choice of law in electronic contracts are also severe, where a choice-of-law provision in a service contract may help in the store-and-forward mode of telemedicine such as teleradiology, its legal validity may be subject to query¹⁶⁵² and the legal effect of the parties' choice cannot be ascertained.¹⁶⁵³

In theory, people are free to choose the law applicable to their contractual obligations. In practice, various approaches have been developed to protect a weaker party to avoid potential injustice.¹⁶⁵⁴ In the 'limited-choice' approach, parties to a contract are allowed to choose between the law of the consumer's habitual residence and the law of the country where the business is established.¹⁶⁵⁵ In the 'unlimited-choice' approach, as it is named, parties are free to choose a law without limits. In between the above two extremes is the 'preferential-law' approach. In Europe, article 5 of the Rome Convention 1980 enacted that parties were allowed to choose the applicable law, but the choice of law should not result in a consumer being deprived of the protection afforded to him or her by the mandatory rules of the law of the country in which the consumer habitually resides.¹⁶⁵⁶ However, article 5 as a mandatory rule was considered not particularly effective to help parties achieve legal certainty or predictability of result, especially in cross-border electronic consumer contracts, as parties to a contract did not know which laws of the consumer's habitual residence would be mandatory and what effect those mandatory rules would have on the contractual choice of law.¹⁶⁵⁷ The Rome Convention 1980 was subsequently replaced by the EC Regulation No. 593/2008 (Rome I Regulation).¹⁶⁵⁸ Article 4(1)(b) of the Rome I Regulation sets out that if parties to a contract have not chosen a law

¹⁶⁵¹ European Commission, Directorate General Information Society (2009) (n 163) 44.

¹⁶⁵² Ibid.

¹⁶⁵³ Zheng Tang, 'Parties' Choice of Law in E-Consumer Contracts' (2007) 3(1) Journal of Private International Law 113, 113.

¹⁶⁵⁴ Ibid.

¹⁶⁵⁵ European Commission, *Green Paper on the conversion of the Rome Convention of 1980 on the law applicable to contractual obligations into a Community instrument and its modernisation* (European Commission, Brussels, 14 January 2003, COM(2002) 654 final) [3.2.7.3 (viii)].

¹⁶⁵⁶ Rome Convention on the law applicable to contractual obligations 1980, art 5(2).

¹⁶⁵⁷ Lorna E Gillies, 'Choice-of-Law Rules for Electronic Consumer Contracts: Replacement of the Rome Convention by the Rome I Regulation' (2007) 3(1) Journal of Private International Law 89, 98.

¹⁶⁵⁸ Non contractual obligations are governed by the EC Regulation No. 864/2007 on the law applicable to non-contractual obligations (Rome II).

applicable to their contract, the law of the country where the service provider has his or her habitual residence prevails. However, if the contract is a consumer contract, i.e. a contract concluded between a consumer and a professional, and the professional (a) pursues his or her commercial or professional activities in the country where the consumer has his habitual residence, or (b) by any means, directs such activities to that country or to several countries including that country, the contract shall be governed by the law of the country where the consumer has habitual residence.¹⁶⁵⁹ Notwithstanding the previous rule, article 6(2) of the Rome I Regulation stipulates that the parties to a consumer contract may still enjoy the freedom to choose the law applicable to the contract, but such a choice cannot deprive consumers of the protection afforded to them by the mandatory provisions of the law of the country where they have their habitual residence. Article 6(4) provides exceptions to this general rule, one of which is that articles 6(1) and 6(2) are not applicable to a contract for the supply of services where the services are to be supplied to the consumer exclusively in a country other than the one in which the consumer has habitual residence. In the US, the Supreme Court of the US in *M/S Bremen v Zapata Off-Shore Co.*¹⁶⁶⁰ held that a party bore a heavy burden of proof if it tried to invalidate on grounds of inconvenience a remote forum selected by parties for treatment of disputes arising out of their contract. It should prove that the agreement was an adhesive one or that the parties did not have the particular controversy in mind when they made their agreement.

In Hong Kong, if parties have expressly chosen a particular law to govern their relationship, subject to exceptions, that particular law will usually be upheld. In the absence of express or implied agreement between the parties, the courts of Hong Kong will adopt a broad principle of ‘closest and most real connection’. If the defendant is not in Hong Kong, the courts of Hong Kong may exercise their discretion to stay proceedings on the ground of *forum non conveniens*. That is to say, the matter before the court may more appropriately be tried in an appropriate forum outside Hong Kong.¹⁶⁶¹

¹⁶⁵⁹ European Commission, Regulation (EC) No. 593/2008 of 17 June 2008 on the law applicable to contractual obligations (Rome I), art 6(1).

¹⁶⁶⁰ 407 U.S. 1, 17, 92 S.Ct. 1907, 1917 (U.S.Fl. 1972) (Supreme Court of the United States).

¹⁶⁶¹ P J Ribeiro and others (eds), *Chitty on Contracts: Hong Kong Specific Contracts* (2nd edn, Sweet & Maxwell, Hong Kong and London 2008) 1323-1324 [15-000]-[15-001].

In China, the Law on the Application of Law for Foreign-Related Civil Legal Relationships of the People's Republic of China¹⁶⁶² came into effect on 1 April 2011 and it is the first legislation to deal with the concerns about conflict of laws. In the area of contract, its article 3 allows parties to a contract to make an express choice of law applicable to their civil matters involving foreign elements, so far as the choice complies with relevant legal provisions. Article 41 states that parties to a contract can choose the governing law and in the absence of a choice of law, the applicable law should be the law of the place where the party who is to effect the characteristic obligation for the contract has habitual residence or the law of another place which has the closest connection with the contract. In the area of tort, article 44 states that the law of 'the place of tort' applies. If the parties have their habitual residences in the same place, the law of that common place applies. If the parties have chosen the governing law for their disputes after the tort happened, that law will apply. Liu warned that attention should be paid when applying this new law. For example, the requirement in article 3 for compliance with relevant legal provisions cannot be construed as 'where law does not prohibit the parties concerned from choosing a governing law, they are free to choose a governing law'; rather, parties are allowed to choose a governing law only when the law specifies so.¹⁶⁶³ Tu commented that while this new law covers modern doctrines in the field of conflict of laws, people still need to refer back to older legal instruments as it is not clear how the Chinese courts will interpret the new statutory provisions.¹⁶⁶⁴ For instance, article 44 does not define 'the place of tort' and it is not clear if it refers to the place where the tortious act was committed or where a party suffered damage.¹⁶⁶⁵ Paragraphs 187 of the Opinions of the Supreme People's Court on Several Issues concerning the Implementation of the General Principles on Civil Law 1988¹⁶⁶⁶ may provide a reference that if parties do

¹⁶⁶² Law on the Application of Law for Foreign-Related Civil Legal Relationships of the People's Republic of China (中華人民共和國涉外民事關係法律適用法; *zhōng huá rén mín gòng hé guó shè wài mín shì guān xì fǎ lǚ shì yòng fǎ*).

¹⁶⁶³ Guixiang Liu, 'Questions About Law Governing Application of Laws to Civil Matters Involving Foreign Elements Expectable in Practical Adjudication (Part II)' (2011) 93(6) China Law 65 (translated by Qingliu Xia), 65.

¹⁶⁶⁴ Guangjian Tu, 'China's New Conflicts Code: General Issues and Selected Topics' (2011) 59(2) The American Journal of Comparative Law 563.

¹⁶⁶⁵ Ibid 583.

¹⁶⁶⁶ China, Opinions of the Supreme People's Court on Several Issues concerning the Implementation of the General Principles on Civil Law (最高人民法院關於貫徹執行中華人民共和國民法通則若干問題的意見; *zuì gāo rén mín fǎ yuàn guān yú guān ché zhí xíng zhōng huá rén mín gòng hé guó mǐn fǎ tōng zé ruò gān wèn tí de yì jiàn*) 1988.

not have a common habitual residence, the court has a discretion to decide which place is the place of tort but it inclines to choose the place where the law is more favourable to the victim.

8.5.1.3 Recognition and Enforcement

A court will consider if it has the jurisdictional power to recognize and enforce a foreign judgment. In the UK, the House of Lords in *Kuwait Airways Corp v Iraqi Airways Co (Nos 4 and 5)*¹⁶⁶⁷ held that in cases concerned a conflict of laws, where the standard being applied by the court was clear and manageable in appropriate circumstances, it was legitimate for an English court to have regard to the content of international law in deciding whether a foreign law would be recognized and contemporary standards used to judge the acceptability of a provision of foreign law. In the case of Hong Kong and China, with a unique establishment of ‘One Country Two Systems’, the relationship between the two territories is not exactly the same as the one between countries. Mere reference to international law may not totally help resolve the issues of recognition and enforcement in a conflict of laws.

8.5.2 Litigation between Hong Kong and another Common Law Country

The author has conducted research and found that as of this writing, there is no lawsuit in the area of telemedicine in Hong Kong. No statute is enacted in Hong Kong to control activities of telemedicine, either. If a claimant brought a clinical negligence action in Hong Kong against a telemedicine health practitioner based in another common law country, or vice versa, and it involves legal disputes on the existence of health practitioner-patient relationship and/or duty of care, it is submitted that in the absence of any legislation in relation to telemedicine, the Hong Kong courts may likely refer to domestic and foreign case law to decide whether a health practitioner-patient relationship has been established online and whether the practitioner owes a duty to the claimant. Case law in the US, the UK, Canada, and Australia, etc. as discussed in previous chapters suggests that courts in Hong Kong may probably take a few principles proposed by Kuszler into account when considering the issue of health practitioner-patient relationship, namely whether the defendant health practitioner has agreed to see a patient online, whether the contents

¹⁶⁶⁷ [2002] UKHL 19, [2002] 2 AC 883 (House of Lords).

of their online telecommunications related to the patient's clinical diagnosis, and whether the patient has relied on the practitioner's advice.¹⁶⁶⁸ Also, the ruling of Supreme Court of New York in *Bienz v Central Suffolk Hospital*¹⁶⁶⁹ that it is a question of fact to decide if a patient's telephone call to a doctor would constitute a physician-patient relationship may likely be extended to other telemedical applications.

8.5.3 Litigation between Hong Kong and China

8.5.3.1 Choice of a Litigation Venue

What makes the situation more complicated is litigation between Hong Kong and a civil-law jurisdiction like China. McLean has provided useful and practical advice on a potential medical negligence lawsuit pertaining to cross-border telemedicine. He compared two scenarios for a hypothetical case where a Chinese tele-patient was injured in a cross-border telemedicine between the US and China.¹⁶⁷⁰ The Chinese patient may file his or her medical negligence claims in the US and faces legal issues in the selection of the forum and jurisdiction, enforcement of the judgment and treatment of the arbitration clause. An US attorney might take the case if the damages are sufficient, the estimated cost to collect evidence in China would be minimally more than the cost to collect similar evidence in the US, and the attorney can find a court with jurisdiction. Alternatively, the Chinese patient may submit the claim in China, but he or she still faces a number of legal challenges, including whether the Chinese court has jurisdiction over a non-resident health practitioner and/or a health institute in the US, the difficulty of getting an American defendant to appear before a Chinese court, and the US government's reluctance to extradite a health practitioner to China for a non major cybercrime case. McLean elaborated that in this hypothetical case, the Chinese patient's suing in a US court would be beneficial as the enforcement of a favourable judgment would not be problematic, but the disadvantages are that there must be substantial damages, otherwise no attorney would consider taking a medical malpractice case, and there would be some difficulty

¹⁶⁶⁸ Kuszler (n 5) 310.

¹⁶⁶⁹ 163 A.D.2d 269, 557 N.Y.S.2d 139 (N.Y.A.D., 1990) (Supreme Court of New York).

¹⁶⁷⁰ McLean, 'International Law, Telemedicine & Health Insurance: China as a Case Study' (2006) (n 1439) 43-45.

in finding a court with jurisdiction. The disadvantage of suing in China is that the US courts are not required to enforce foreign judicial awards.¹⁶⁷¹

The issue of damages in the above hypothetical case is a significant and real consideration in a cross-border telemedicine lawsuit, as the systems of award of damages may be different at both ends of the telemedical practice. In China, medical accidents are classified into four grades in accordance with the seriousness of patient injury, ranging from the most serious grade involving death or serious disability to the least serious one causing ‘obvious injury to the body of patients or other consequences’.¹⁶⁷² In deciding the quantum of damages, a court will consider the following factors: the grade of injury in the medical accident, the seriousness of the medical negligent act causing the injury, and the relationship between the injury caused by the medical accident and the patient’s original illness.¹⁶⁷³ Articles 49-52 and 53-59 of the Chinese HMA Regulation 2002 contain detailed calculation methods and the ‘punishment’ provisions. On top of the award of damages, health authorities may also follow the current laws, regulations and ministerial rules to give ‘administrative punishments’ to medical institutions and the staff concerned.¹⁶⁷⁴ In Hong Kong, different headings of general damages will be considered in medical negligence cases. When a claimant proceeds with a claim, he or she has to serve a statement of damages on the defendant, stating the amount of general damages claimed for pain, suffering and loss of amenities and damages for loss of earning capacity, as well as damages for loss of society.¹⁶⁷⁵

8.5.3.2 Enforcement of Judgment

McLean’s example has not included all the issues for a patient’s claim between Hong Kong and China in the area of enforcement of a foreign judgment. To follow the common law practice, apart from the question as to whether a foreign judgment involves a debt or a definite sum of money, the Hong Kong court will also

¹⁶⁷¹ Vaughan Black, ‘Canada and the US Contemplate Changes to Foreign-Judgment Enforcement’ (2007) 3(1) *Journal of Private International Law* 1, 3.

¹⁶⁷² Regulation on the Handling of Medical Accidents of People’s Republic of China (中華人民共和國醫療事故處理條例; *zhōng huá rén mín gòng hé guó yī liáo shì gù chǔ lǐ tiáo lì*) 2002, art 4.

¹⁶⁷³ *Ibid* art 49.

¹⁶⁷⁴ *Ibid* art 35.

¹⁶⁷⁵ Hong Kong, Judiciary, *Practice Direction 18.1*, [65.2].

consider whether a foreign judgment is final and conclusive.¹⁶⁷⁶ The first case questioning the finality of judgment of a court in China was *Chiyu Banking Corporation Limited v Chan Tin Kwun*,¹⁶⁷⁷ which was a case heard before the High Court (named ‘the Court of First Instance’ after the changeover of sovereignty in 1997). The claimant was a bank in China and obtained judgment in the Fujian Intermediate People’s Court of China (a provincial court) against the defendant as guarantor. The defendant appealed to the Higher People’s Court in the same province and the decision of the original court was affirmed. However, it was not the end of the story. In late 1995, the Fujian People’s Procuratorate received the defendant’s petition for a retrial of the action conducted by the intermediate court. Under the legal system of China, the Procuratorate can exercise a supervisory function over civil adjudication by the courts. In particular, under article 185 of the Civil Procedure Law 1991 of China, the Fujian People’s Procuratorate is entitled to refer the matter to the Supreme People’s Procuratorate for consideration of whether a protest would be lodged with the court in respect of a judicial decision. Upon receipt of the protest, the court is required to conduct a retrial under article 187 of the Civil Procedure Law. In early 1996, the Fujian People’s Procuratorate reported to the Supreme People’s Procuratorate and requested it to lodge a protest. The defendant submitted to the High Court of Hong Kong that in view of the actions of the Chinese Procuratorate, the case should not be allowed to proceed further, as there was a possibility of reaching a different result when the court in China retried the case. The defendant asserted that the legal proceedings in Hong Kong should be stayed to avoid multiplicity of actions. The claimant accepted that the proper forum for resolution of the dispute was the court in Fujian but argued that the judgment of the Fujian Intermediate Court was final and conclusive and the consideration of the forum was no longer relevant. The High Court in Hong Kong held that the court must consider the finality of a foreign judgment and that the judgment must be final and conclusive before the judgment could be enforced. A foreign judgment is considered final if it can be established that it is final and unalterable in the court which pronounced it and cannot thereafter be modified. In case of pending appeal, the judgment must be assumed to be valid until a higher court rules otherwise. In the present case, the

¹⁶⁷⁶ Michelle Tsang, ‘A New Chapter in Reciprocal Enforcement of Judgements between the Mainland and Hong Kong’ (July 2008) *Hong Kong Lawyer* 59, 60

¹⁶⁷⁷ [1996] 2 HKLR 395 (High Court).

supervisory function of the Supreme People's Procuratorate and the protest system were not simply an appeal process. Under this system, the Fujian Intermediate Court could alter its decision on a retrial if the Supreme People's Procuratorate lodged a protest in accordance with the Civil Procedure Law of China. As the court in Fujian retained the potential to modify its own decision, the High Court of Hong Kong considered the original judgment not final or conclusive, and ordered that the legal proceedings in Hong Kong would be stayed pending the decision of the Supreme People's Procuratorate. The Court of Appeal in *Lam Chit Man v Lam Chi To*,¹⁶⁷⁸ a case heard after the change of sovereignty of Hong Kong, approved *Chiyu Banking Corporation Limited v Chan Tin Kwun*. In *Lee Yau Wing v Lee Shui Kwan*,¹⁶⁷⁹ the Court of Appeal held that the issue of whether the supervision system of the Supreme People's Procuratorate under the Civil Procedure Law of China rendered a judgment in China inconclusive and not final was an issue of public importance and involved complicated legal questions that could not be determined in the absence of trial. Huang argued that the court in Hong Kong inappropriately applied the law of the requested court to determine the finality of a Chinese judgment in the context of judgment recognition and enforcement. He proposed three solutions to fix the finality dispute between Hong Kong and China: amending either the laws of Hong Kong or China or approaching the issue from a perspective of interregional law.¹⁶⁸⁰

Under the principle of 'One Country Two Systems', in order to establish a new and convenient mechanism for the reciprocal enforcement of courts' judgments made in China and Hong Kong and to reduce the time and money spent by a judgment creditor in bringing a legal action again in the place where the property of the debtor is situated,¹⁶⁸¹ Hong Kong and China signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned¹⁶⁸² (the

¹⁶⁷⁸ [2001-2003] HKCLR 141, [2001-2003] HKCLR 133 (Court of Appeal).

¹⁶⁷⁹ [2007] 2 HKLRD 749, [2007] CHKEC 867 (Court of Appeal).

¹⁶⁸⁰ Jie Huang, 'Conflicts Between Civil Law and Common Law in Judgement Recognition and Enforcement: When is the Finality Dispute Final?' (2011) 29(1) Wisconsin International Law Journal 70.

¹⁶⁸¹ Hong Kong Government, 'Speech by Secretary for Justice (Press Release, 14 July 2006)' <<http://www.info.gov.hk/gia/general/200607/14/P200607140156.htm>> accessed 28 June 2012.

¹⁶⁸² '關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排' (*guān yú nèi dì yǔ xiāng gāng tè bié xíng zhèng qū fǎ yuàn xiāng hù rèn kě hé zhí xíng dāng shì rén xié yì guān xiá de mǐn shāng shì àn jiàn pàn jué de ān pái*) in Chinese.

‘Arrangement’) in July 2006 to deal with pecuniary judgments on contractual disputes arising from civil or commercial matters whereby the parties to the disputes have made a prior express agreement to submit the dispute to a court in either Hong Kong or China.¹⁶⁸³ In the absence of a generally accepted definition of ‘commercial matters’, the Arrangement defines its scope by way of exclusion through international conventions such as the Hague Convention 2005 and the UN Convention on Contracts for the International Sale of Goods.¹⁶⁸⁴ The Arrangement became effective on 1 August 2008. Article 2 of the Arrangement expressly states that in the case of China, ‘an enforceable final judgment’ means (a) any judgment made by the Supreme People’s Court, any judgment of the first instance made by a Higher or Intermediate People’s Court or a Basic People’s Court authorized to exercise jurisdiction of the first instance in civil and commercial cases involving foreign, Hong Kong, Macao and Taiwan parties, (b) from which no appeal is allowed or in respect of which the time limit for appeal has expired and no appeal has been filed, as well as (c) any judgment of the second instance and any judgment made following the procedure for trial supervision by bringing up the case for a retrial by a people’s court at the next higher level. In the case of Hong Kong, ‘an enforceable final judgment’ means any legally effective judgment made by the Court of Final Appeal, the Court of Appeal and the Court of First Instance, and the District Court.

Correspondingly in 2008, the Mainland Judgments (Reciprocal Enforcement) Ordinance¹⁶⁸⁵ was enacted in Hong Kong. Its section 3(3)(b) expressly stipulates that the agreed choice of a Hong Kong court or a Mainland court to determine a dispute does not apply to an electronic contract by means of an electronic data message, a telegram, a telex, a facsimile, an electronic data interchange or an electronic mail unless it is concluded or evidenced that the agreement is capable of being displayed in visible form and information is accessible so as to be usable for subsequent reference. Section 16 provides that any judgment in China, upon the requirements stipulated in sections 5(1) and 5(2)(a)-(e), will be recognized in any court in Hong Kong as conclusive between the parties to the judgment in any proceedings founded on the same cause of action and may be relied on by way of defence or counterclaim in any such proceedings, except where the registration of the

¹⁶⁸³ Tsang (n 1676) 60.

¹⁶⁸⁴ Ibid.

¹⁶⁸⁵ Cap 597.

judgment has been or would have been set aside under sections 18 and 19. Its section 6(2) specifies that a Mainland judgment is deemed to be enforceable, until the contrary is proved, if it is accompanied by a certificate issued by the relevant court certifying that the judgment is final and enforceable in the Mainland.

8.5.3.3 Patients' Probable Preference

In the context of cross-border telemedicine between Hong Kong and China, in theory, a patient may proceed with his or her claim either in Hong Kong or China to sue a tele-health practitioner, and the issue of enforcing a judgment obtained in a Chinese court seems to be less difficult under the Arrangement than in the time of *Chiyu*.¹⁶⁸⁶ However, this may not reflect the truth in practice. To be in line with the observation that many foreigners were hesitant to pursue their legal rights in China for fear of its lack of the rule of law and an independent judicial system,¹⁶⁸⁷ He has said that Chinese people also lose confidence in the courts in China and distrust the competence of the Chinese legal system that they try their own best to take measures to self protect their interests in business,¹⁶⁸⁸ although another recent survey showed that the Chinese were significantly more confident than Taiwanese in their respective courts.¹⁶⁸⁹ If He's finding correctly describes the current mentality of people in China, a patient involved in an alleged telemedical adverse event may prefer commencing a claim and enforcing any court judgment in Hong Kong.

8.6 Alternative Dispute Resolution

A medical dispute will ruin the relationship between a health practitioner and a patient, which is built with 'vulnerability and trust on one side and caring and professional expertise on the other.'¹⁶⁹⁰ Whilst many medical disputes follow an adversarial path like litigation, 'even a worthy plaintiff is very unlikely to receive

¹⁶⁸⁶ [1996] 2 HKLR 395 (High Court).

¹⁶⁸⁷ Mo Zhang, 'International Civil Litigation in China: A Practical Analysis of the Chinese Judicial System' (2002) 25(1) Boston College International and Comparative Law Review 59, 63.

¹⁶⁸⁸ Xin He, 'Court Finance and Court Responses to Judicial Reforms: A Tale of Two Chinese Courts' (2009) 31(4) Law & Policy 463, 474.

¹⁶⁸⁹ Yung-Lien Lai, Liqun Cao, Jihong Solomon Zhao, 'The impact of political entity on confidence in legal authorities – A comparison between China and Taiwan' (2010) 38(5) Journal of Criminal Justice 934.

¹⁶⁹⁰ Henry Brown and Arnold Simanowitz, 'Alternative dispute resolution and mediation' (1995) 4(2) Quality in Health Care 151, 151.

compensation via a judicial route.’¹⁶⁹¹ Furthermore, the reasons why claimants sue health practitioners are many-fold. They may not do so for money, but for other considerations such as principles,¹⁶⁹² explanations or apologies.¹⁶⁹³

Disputants involved in a claim involving cross-border telemedicine may consider the Alternative Dispute Resolution (ADR) mechanisms such as arbitration and mediation. ‘The idea that justice has no price tag is unacceptable in the modern world. Our civil system must mend its ways and provide every court user ... with a dispute resolution system at a proportionate cost’, said Jackson LJ.¹⁶⁹⁴ If parties to a cross-border telemedicine dispute prefer ADR to litigation, they may include ADR terms in their contracts before any substantial disputes arise. As discussed in Chapter 7, there is a need for caution if arbitration terms are incorporated into a contract of telemedicine, as how such terms are drafted may affect their enforceability in certain jurisdictions, as illustrated by American cases, *Cannon v Lane*¹⁶⁹⁵ in Oklahoma and *Broemmer v Abortion Services of Phoenix, Ltd*¹⁶⁹⁶ in Arizona. Elliott has also explored the use of medical malpractice arbitration in the managed care setting in the US and she concludes that there are contractual and constitutional concerns and healthcare reform is required before the mandatory use of arbitration is viable and any reform should not harm the interests as well as the contractual and constitutional rights of patients.¹⁶⁹⁷ In addition to arbitration, parties may also consider mediation which is an ADR alternative to arbitration for conflict management, where parties in a dispute seek the assistance of an impartial third party to settle their conflict or resolve their differences without invoking the authority of law.¹⁶⁹⁸ The success of mediation depends highly on the mutual desire of the disputants to resolve their grievances¹⁶⁹⁹ without resort to other adversarial means.

¹⁶⁹¹ McLean, ‘International Law, Telemedicine & Health Insurance: China as a Case Study’ (2006) (n 1439) 45.

¹⁶⁹² Tamara Relis, ‘“It’s Not About the Money!”: A Theory on Misconceptions of Plaintiffs’ Litigation Aims’ (2006-2007) 68(3) University of Pittsburgh law review 701, 743.

¹⁶⁹³ Vincent, Young and Phillips (n 859) 1609.

¹⁶⁹⁴ Jackson LJ, as cited in Dominic Regan, ‘Jackson on Jackson’ *Counsel* (London, May 2012) 17, 17.

¹⁶⁹⁵ 867 P.2d 1235, 1240, 16 Employee Benefits Cas. 2783, 1993 OK 40 (Okla., 1993) (Supreme Court of Oklahoma).

¹⁶⁹⁶ 173 Ariz. 148, 150, 840 P.2d 1013, 1015 (Ariz., 1992) (Supreme Court of Arizona).

¹⁶⁹⁷ Amy E Elliott, ‘Arbitration and Managed Care: Will Consumers Suffer if the Two are Combined’ (1994-95) 10(2) Ohio State Journal on Dispute Resolution 417.

¹⁶⁹⁸ Jacob Bercovitch, J Theodore Anagnoson and Donnette L Wille, ‘Some Conceptual Issues and Empirical Trends in the Study of Successful Mediation in International Relations’ (1991) 28(1) Journal of Peace Research 7, 8.

¹⁶⁹⁹ Stephen B Goldberg, ‘The Mediation of Grievances Under A Collective Bargaining Contract: An Alternative to Arbitration’ (1982) 77(3) Northwestern University Law Review 270, 283.

8.7 The Ways Forward

8.7.1 Legislation

The legal development in telemedicine in both Hong Kong and China has lagged behind other developed jurisdictions such as the US and the EU for at least a decade. California enacted a new Telehealth Advancement Act in 2011 to replace its Telemedicine Development Act legislated in 1996.¹⁷⁰⁰ Malaysia also passed its Telemedicine Act in 1997. If the term ‘clinical iceberg’ is used to describe the visible part of a disease as the ‘tip of the iceberg’, leaving a significantly greater part of the disease subject to further investigation,¹⁷⁰¹ ‘legal iceberg’ may be used to describe the current legal situation of telemedicine practice in Hong Kong and China. Without sufficient legal protection, it would not be fair to those telemedicine health practitioners who work hard to improve incessantly patient safety and enhance healthcare quality.¹⁷⁰² Their good wishes, ironically, may not protect themselves sufficiently in the legal sense when they undergo telemedicine to help patients in remote areas, without realizing a legal loophole is on the way ahead waiting for them.

Enactment of telemedicine law in Hong Kong and China will advance public health by statutorily enhancing people’s right to have equitable access to healthcare service, defining the scopes and objectives of telemedicine,¹⁷⁰³ and clearing a certain degree of legal uncertainty to help the growth of telemedicine in the two territories, no matter whether it is a cross-border practice or not. Making telemedicine law will not only provide better legal protection for stakeholders in telemedicine practice, but also facilitate health institutes and practitioners to arrange telemedicine insurance coverage and allow patients to understand their legal rights when they enjoy this state-of-the-art delivery of healthcare services. As put forward by Rannefeld, with apparent telemedicine laws in place, health practitioners will become less uncertain as to where a claim may arise and will no longer have doubt as

¹⁷⁰⁰ ‘California Signs Telehealth Advancement Act’ (n 249).

¹⁷⁰¹ K M Choy, P Wong, and W M Ko, ‘The evolution of complaint management in the Hong Kong Hospital Authority. Part 2: The ‘complaints’ iceberg’ (2004) 10(5) Hong Kong Medical Journal 362, 362.

¹⁷⁰² Arthur A Levin (n 873) 94.

¹⁷⁰³ For example, consultation through telephone or facsimile machine is expressly excluded from the statutory definition of the Oklahoma Telemedicine Act 1997. See §36-6802.

to which standard of care should apply.¹⁷⁰⁴ This enhancement of legal certainty will not only eliminate problems in jurisdictional ‘venue shopping’ and health practitioners’ practice of telemedicine in a territory with a lower standard of care to avoid liability, but encourage more health practitioners to commence using telemedicine in daily practices as well.¹⁷⁰⁵ Also, telemedicine laws help building a trusting health practitioner-patient relationship, as practitioners will understand the legal standard in the provision of telemedical applications.¹⁷⁰⁶

In the process of drafting the law, both Hong Kong and China may consider using a model-law concept like the across-state-line model act accepted by the Federation of State Medical Boards of the US.¹⁷⁰⁷ This model-law concept helps reduce, if not eliminate, legal incompatibility in the context of telemedicine practice between Hong Kong and China. Legal incompatibility in the current medical laws of the two jurisdictions include, for instance, how to decide whether a health practitioner’s practice is up to a reasonable standard of care (the *Bolam*¹⁷⁰⁸ principle as modified by *Bolitho*¹⁷⁰⁹ at common law vs a over-50% majority passed by the experts in the technical authentication process as stipulated in article 31 of the Chinese HMA Regulation 2002) and how much information is considered reasonably sufficient for patients to give consent (the three common-law approaches, namely provider-centred, patient-centred, and purely subjectively individual-based¹⁷¹⁰ vs article 11 of the Chinese HMA Regulation 2002 requiring ‘truthful’ and timely information to patients). The enactment of respective electronic signature laws in the two territories based on the 1996 UNCITRAL Model Law on Electronic Commerce published by the UN has provided a good example to reduce legal incompatibility in electronic signatures.

8.7.2 ‘One Country Two Systems’

The concept of ‘One Country Two Systems’ began in 1978¹⁷¹¹ when Deng Xiaoping started to deal with the issue of reunification of China with Hong Kong,

¹⁷⁰⁴ Lisa Rannefeld, ‘The Doctor Will E-mail You Now: Physicians’ Use of Telemedicine to Treat Patients over the Internet’ (2004-05) 19(1) *Journal of Law and Health* 75, 102.

¹⁷⁰⁵ *Ibid.*

¹⁷⁰⁶ *Ibid.*

¹⁷⁰⁷ Federation of State Medical Boards of the United States (1996) (n 39).

¹⁷⁰⁸ [1957] 1 WLR 582, [1957] 2 All ER 118 (High Court Queen’s Bench).

¹⁷⁰⁹ [1998] AC 232, [1997] 4 All ER 771 (House of Lords).

¹⁷¹⁰ Altman, Parmelee and Smyer (n 881) 300.

¹⁷¹¹ Michael Yahuda, ‘Deng Xiaoping: The Statesman’ (1993) 135 *The China Quarterly* 551, 568.

Macau and Taiwan. After the handover of Hong Kong in 1997, increasing legal cooperation between China and Hong Kong, though it is still ‘kept to a minimum’, has been observed and the reciprocal recognition and enforcement of civil and commercial judgments by the courts of China and Hong Kong as stipulated in the Arrangement is a recent example.¹⁷¹² In relation to licensing and credentialing of health practitioners between Hong Kong and China, CEPA and ‘the Administrative Measures for Hong Kong and Macao Doctors to Obtain Mainland’s “Medical Practitioner’s Qualification Certificates” through Accreditation’ promulgated by the Ministry of Health and the State Administration of Traditional Chinese Medicine of China¹⁷¹³ have laid a basic foundation for mutual recognition of professional qualifications. To better facilitate the delivery of cross-border telemedicine services, the governments in the two territories may wish to base on the current foundation to further help telemedicine health practitioners to practise telemedicine between Hong Kong and China. For example, in the aforesaid across-state-line model act of the Federation of State Medical Boards of the US,¹⁷¹⁴ a special licence is recommended for doctors practising telemedicine across state lines of the US and no licence for out-of-state doctors in a patient’s state is suggested in emergency cases and in informal doctor-doctor consultations without financial compensation to an advising doctor.

8.7.3 Professional Codes and Conduct

‘We walk by faith, not by sight’.¹⁷¹⁵ The Medical Council of Hong Kong decided in 2000 not to draw up detailed guidelines to govern its members’ professional conduct and a code because ‘the issue involved was complicated and fast changing’;¹⁷¹⁶ rather, it examined the Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine adopted by the World Medical Association and highlighted the following three points: establishment of a sound doctor-patient relationship, reliable identification of each other, and preference of

¹⁷¹² Albert H Y Chen, ‘The Rule of Law under “One Country, Two Systems”: The Case of Hong Kong 1997-2010’ (2011) 6(1) National Taiwan University Law Review 269, 293.

¹⁷¹³ China, Administrative Measures for Hong Kong and Macao Doctors to Obtain Mainland’s “Medical Practitioner’s Qualification Certificates” through Accreditation (Health and Medical Policy (2009) No. 33) (‘香港和澳門特別行政區醫師獲得內地醫師資格認定管理辦法’, 衛醫政發 (2009) 33 號; ‘xiāng gǎng hé ào mén tè bié xíng zhèng qū yī shī huò dé nèi dì yī shī zī gé rèn dìng guǎn lǐ bàn fǎ’, wèi yī zhèng fā (2009) 33 hào).

¹⁷¹⁴ Federation of State Medical Boards of the United States (1996) (n 39).

¹⁷¹⁵ 2 Corinthians 5:7.

¹⁷¹⁶ Medical Council of Hong Kong (2000) (n 1069) 2.

direct consultation over teleconsultation.¹⁷¹⁷ With due respect, the mentality of not doing something right because an issue is ‘complicated and fast changing’ is somewhat akin to an ostrich policy. ‘The real question about the future of telemedicine is not whether it is here to stay but rather the extent to which we have the foresight to exploit fully the capability of the technology to serve prevailing health care needs’, said Sanders and Bashshur.¹⁷¹⁸ In other developed countries, professional guidelines and legal safeguards for patients were developed approximately two decades ago. In the US, the National Council of State Boards of Nursing started to study a multi-state licensure system to facilitate tele-nursing across state lines in the mid 1990s.¹⁷¹⁹ California enacted its Telemedicine Development Act in 1996 and has even updated this ‘old’ legislation by enacting a new Telehealth Advancement Act 2011.¹⁷²⁰ Wootton once said that Hong Kong would play an important role in the global development of telemedicine,¹⁷²¹ but such role might have faded away at least from the legal and professional perspectives because of the slow progress in developing a robust approach to telemedicine. On the same day in late June 2012, a local newspaper in Hong Kong reported two cross-border applications between Hong Kong and other Chinese cities: the cooperation between Hong Kong and Macau to share electronic bone-marrow donors’ databases for leukemia patients¹⁷²² and the cooperation among Hong Kong and other 16 cities in the Guangdong Province for mutual digital recognition of transportation smartcards developed in the respective cities.¹⁷²³ Cross-border cooperation between Hong Kong and other cities in China has been developing and it is a way of no return. If the development of telemedicine especially in the legal and professional aspects still lags behind, proper protection to patients, health practitioners and health institutes may not run in parallel with the growth of cross-border patient needs between Hong Kong and China.

¹⁷¹⁷ Ibid.

¹⁷¹⁸ Sanders and Bashshur (1995) (n 32) 123.

¹⁷¹⁹ Simpson (n 746).

¹⁷²⁰ ‘California Signs Telehealth Advancement Act’ (n 249).

¹⁷²¹ Wootton (1998) (n 1445) 260.

¹⁷²² Sharing of Bone-Marrow Databases between Hong Kong and Macau (‘港澳骨髓資料互通’; *gǎng ào gú suǐ zī liào hù tōng*) *Mingpao* (Hong Kong, 29 June 2012).

¹⁷²³ ‘Octopus Card Amalgamated with 16 Cities in Lingnan of the Guangdong Province, Without Shenzhen’ (‘八達通嶺南合一 粵 16 城通用深圳無份’; *bā dá tōng lǐngnán hé yī , yuè 16 chéng tōng yòng shēn zhèn wú fèn*) *Mingpao* (Hong Kong, 29 June 2012).

8.7.4 Organizational and Professional Mentality of the Stakeholders

The quality of health services in Hong Kong is good, if not excellent, as identified by a survey,¹⁷²⁴ as opposed to the inequitable access to health services in China because of people's lack of means¹⁷²⁵ as pointed out at the beginning of this chapter. This contrast may be improved through telemedicine. Experiences in other countries have shown that telemedicine is one of the alternatives to the traditional delivery mode of health care and is effective in upholding patients' rights to health and the right of access to health care. If Hong Kong makes use of its healthcare expertise and better employs the state-of-the-art telemedicine for delivering health care, providing professional continuous developments for their counterparts in China, and educating the public about health, it will definitely make a difference. It is not a myth as there are always reports that Hong Kong health practitioners volunteer themselves and go to China to help patients there. For example, the Hong Kong Lifeline Express provided free services to restore the eyesight of over 110,000 patients with cataracts for the period of 1997 to 2010 and exchanged medical expertise with health practitioners in China.¹⁷²⁶ Operation Concern has organized 350 volunteers including surgeons, nurses and therapists from Hong Kong to deliver health services to patients in rural areas in China. In order for the services to be sustainable, they also provide training to enhance the standards of local practitioners.¹⁷²⁷

Volunteerism alone may not totally solve the problem of inequitable access to health care¹⁷²⁸ in China. In view of the limited number of studies in the context of Hong Kong-China cross-border telemedicine in areas not exclusive to the legal aspects, additional surveys are required to address the efficacy of telemedicine.¹⁷²⁹ When chances of empirical studies in the future come, the author wishes not to further receive passive responses like 'we are not able to participate in the study due

¹⁷²⁴ Lam (n 1435) 151-152.

¹⁷²⁵ Meina Liu and others (n 1434) 770, Table 2.

¹⁷²⁶ Hong Kong Lifeline Express, 'The Story' <http://lxenglish.com/lxenglish/article/171fb2589f73f2e5b4a6ca52db5737f7_136.html> accessed 1 July 2012.

¹⁷²⁷ Operation Concern, 'What we Work' <<http://www.operationconcern.org/oc/eng/service/work.htm>> accessed 1 July 2012.

¹⁷²⁸ Kim E Barnhill, Leslie M Beitsch and Robert G Brooks, 'Improving Access to Care for the Underserved: State-Supported Volunteerism as a Successful Component' (2001) 161(8) *Journal of American Medical Association* 2177, 2181.

¹⁷²⁹ Constantine A Manthous, 'Leapfrog and Critical Care: Evidence- and Reality-Based Intensive Care for the 21st Century' (2004) 116(3) *The American Journal of Medicine* 188, 191.

to limited resources’,¹⁷³⁰ ‘telemedicine is still in an infant stage ... and there are hardly any specific laws or regulations governing such practice’, ‘[h]aving regard to its statutory powers and functions, the [institute] is not in the position to render any assistance to you’,¹⁷³¹ ‘there is no subject officer overseeing telemedicine in the [institute and] we do not have documents relating to your requests’,¹⁷³² ‘the [institute] does not have the documentation or information on telemedicine’,¹⁷³³ or get irrelevant feedback like ‘in Hong Kong, there is no legal definition for the term “dietary supplement”’.¹⁷³⁴ Rather, the author is eager to get some proactive messages like ‘we do not do any telemedicine in this [h]ospital ... we do foresee that in the next few years we may be doing this [and a] timely research will be of interest to us in the future’.¹⁷³⁵ While the author’s wishes are personal, the meaning behind such wishes is the change of organizational and professional mentality as well as the re-prioritization of resources. It is the author’s humble wish that this study is successful in at least arousing the interests of some stakeholders with authority in checking the need for cross-border telemedicine, not for today but for tomorrow, and examining the current legal readiness to support the sustainable growth of telemedicine in Hong Kong, China and across the two territories. A large sum of the budget has been spent in Hong Kong and China to establish healthcare systems such as EHRs,¹⁷³⁶ but such systems may become downstream products if reasonable and sufficient legal protection to patients and other stakeholders in the healthcare industry has not been addressed upstream.

8.8 Conclusion

‘In a time of unprecedented mobility, there is no justification for distance to compromise health or disease management’, said Murrell.¹⁷³⁷ While health is

¹⁷³⁰ Private correspondence dated 5 January 2008 between the Shatin International Medical Centre Union Hospital and the author.

¹⁷³¹ Private correspondence dated 14 January 2008 between the Medical Council of Hong Kong and the author.

¹⁷³² Private correspondence dated 14 January 2008 between the Hospital Authority of Hong Kong and the author.

¹⁷³³ Private correspondence dated 18 February 2008 between the Faculty of Medicine of the University of Hong Kong and the author.

¹⁷³⁴ Private email communication dated 23 January between the Department of Health of Hong Kong and the author.

¹⁷³⁵ Private correspondence dated 21 January 2008 between the Hong Kong Adventist Hospital and the author.

¹⁷³⁶ Hong Kong, eHealth Record Office (n 1614) and Liang and others (n 206) 281.

¹⁷³⁷ Merrell (2004) (n 1238) 149.

considered internationally as a basic right, how to improve people's equitable access to healthcare services has become an important global concern. With the advent of information technology, telemedicine has changed the methods of communication between health practitioners and patients and improved service quality for populations in remote areas. Telemedicine is not only a state-of-the-art technology in healthcare delivery, but more importantly, it enhances people's right to equitable access to healthcare services as well. However, the growth of telemedicine in the past decade was retarded because of legal uncertainty in its applications.

This study may be the first one to examine the medico-legal liability of practising cross-border telemedicine in Hong Kong and China. This research has referred to international treaties, federal law, national statutes, subsidiary law, case law, professional regulations and guidelines, and official reports of foreign and domestic sources, and made use of a European legal framework, namely the SIREN model, to analyze legal issues embedded in telemedicine, with special reference to cross-border telemedicine practice between Hong Kong and China. The areas of liability covered in this study include medical liability, patient safety, data protection principles, patient liability, organizational liability, service liability, product liability, contractual liability and criminal liability. Also, in the context of 'One Country Two Systems' in Hong Kong and China, this study has examined the conflict of laws in the delivery of cross-border telemedical health care.

At the time of writing this thesis, in 2011/2012, there is no telemedicine legislation in Hong Kong and China. There is no news on whether the Chinese and Hong Kong governments will enact legislation in the future to safeguard the people's rights and interests in telemedicine. There is no idea on whether there will be authoritative case precedents in other countries to guide the legal development of telemedicine. Against this background, the author has conducted a wide range of legal research and a literature review before he put forward his best 'guesstimates' on the possible areas that will make health practitioners and institutes susceptible to medico-legal liability in the cross-border telemedicine practice between Hong Kong and China. The author has also proposed the ways forward in the better development of cross-border telemedicine practice between the two territories. The author hopes such educated guesses and proposals will help governments, leaders of professional bodies and health institutes, health practitioners, patients, the general public and other stakeholders in the two territories to at least be aware of the medico-legal risks, an

area to which they may not have paid sufficient attention, and hopefully may further help them step up their awareness and allocate more necessary resources to address the potential risks.

To end this thesis, the author would like to borrow Millenson's words as follows,

There is a world of difference between calling for a revolution and actually leading one. (And, yes, the latter is far riskier to one's professional well-being.) That difference is why the quality improvement movement, it pains me to say, remains essentially a sideshow for most providers and most of the public.¹⁷³⁸

'Today is already tomorrow'.¹⁷³⁹ If Hong Kong or China does not start a robust planning about telemedicine, then as what a proverb has similarly said, today will definitely become the tomorrow people worried about yesterday.

*** End ***

¹⁷³⁸ Michael L Millenson, 'The Silence' (2003) 22(2) Health Affairs 103, 111.

¹⁷³⁹ London (n 1246) 153.

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Private Correspondences

Letter dated 5 January 2008 from the Shatin International Medical Centre Union Hospital.

Letter dated 8 January 2008 from the Hong Kong Sanatorium & Hospital.

Letter dated 14 January 2008 from the Medical Council of Hong Kong.

Letters dated 14 and 18 January 2008 from the Hospital Authority of Hong Kong.

Letter dated 21 January 2008 from the Hong Kong Adventist Hospital.

Email dated 23 January 2008 from the Department of Health of Hong Kong.

Letter dated 18 February 2008 from the Faculty of Medicine of the University of Hong Kong.

Appendix

A sample of letters and reminders
sent to selected stakeholders in Hong Kong
for the proposed empirical research

31 December 2007

(Address)

Dear XXXX,

Legal Research in Telemedicine

I am a Doctor of Juridical Science (part time) student of the School of Law of the City University of Hong Kong researching, under the direction of Professor XXXX, some aspects of medico-legal liability in offsite telemedicine practice in Hong Kong and Mainland China. The study involves examining law and regulations governing telemedicine, liability of clinical professionals and rights of patients in the course of telemedicine practice. Annex 1 contains a background brief on the study.

In view of the important part your Hospital plays in Hong Kong's healthcare system, your input will greatly assist me in my research. I should be grateful to you if you could kindly consent to the release of information and documents that I have detailed in Annex 2. I also seek your consent to quote such information and documents in my research outputs.

Alternatively, could you please allow me access to documents and material under your control for me to gather the relevant information? Could you also kindly give me an opportunity to interview relevant officers in your Hospital?

I can be contacted on (852) XXXX and my email address is XXXX. My student number is XXXX. Please direct any inquiries about my student status to (a university staff), School of Graduate Studies of CityU (tel.: (852) XXXX; fax: (852) XXXX; email: XXXX).

I look forward to your favourable reply. Thank you.

Yours sincerely,

(Kar-wai TONG)

c.c. Concerned departments and staff of the City University of Hong Kong

Legal Research in TelemedicineBackground brief

As defined by the American College of Physicians telemedicine is: “the use of audio, video, and other telecommunications and electronic information processing technologies to provide health services or assist health care personnel at distant sites”¹. The U.S. Food and Drug Administration of the United States defines it as “the delivery and provision of healthcare 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”².

Use of telecommunication in the healthcare field could be traced back to early 1900s and has been gathering momentum around the world, e.g. in Japan, the United States, Russia, Australia, Hong Kong³ and the Mainland China⁴. This global growth can be attributed to the following factors⁵:

- (a) widely available and cheap communication
- (b) Low cost, high performance computers
- (c) Greater public confidence in the use of computer technology,
- (d) Greater acceptance of the technology by medical professionals, and

¹ American College of Physicians, “Telemedicine Glossary”.

<<http://www.acponline.org/computer/telemedicine/glossary.htm#T>> accessed 24 December 2007.

² United States Food and Drug Administration, *Appended report on telemedicine-related activities of the Centre for Devices and Radiological Health, FDA* (11 July 1996).

<<http://www.fda.gov/cdrh/telemed.html#activities>> accessed 26 December 2007.

³ *Telemedicine Today*.

<<http://72.14.203.104/search?q=cache:GD6wCRAJJ8sJ:www2.telemedtoday.com/articles/international.shtml+Hong+Kong+Telemedicine+law&hl=zh-TW>> accessed 5 December 2005. See also B.L. Crowe and I.G. McDonald, “Telemedicine in Australia, Recent Development” in *Journal of Telemedicine and Telecare*, 3(4), 1 December 1997, 188-193.

⁴ R. Hsieh, N.M. Hjelm, J.C.K. Lee, and J.W. Aldis. “Telemedicine in China”, in *International Journal of Medical Informatics*. 61, 2001. 139-146.

⁵ California Telemedicine & eHealth Center.

<http://www.cttconline.org/telemedicine_history.html> accessed 5 December 2005.

- (e) Ever improving standards in communications, video conferencing, and medical disciplines

Telemedicine can help provide quality service to patients in remote areas which are otherwise almost inaccessible. In view of increasing people movements in the wave of globalization, it is anticipated that the demands for cross-border and cross-country clinical services will grow. Telemedicine as a means of conducting medicine through the use of information technologies and the Internet may be a cost-effective solution to meet these global demands.

Cross-border telemedicine practice involves complex legal issues. Examples include jurisdiction of courts in different countries for a medical negligence case arising from the practice; different licensure & credentials requirements for healthcare professionals; new clinician-patient relationship; new standard of care due to technological advancement affecting the assessment of medical negligence; and protection of patients' electronic medical records. A survey conducted in 2000 in Canada found that only 29% of the respondents knew that videoconferencing is a means of conducting medical tests and making diagnoses, while 87.8% concerned responsibility and liability for malpractice and errors in telemedicine and 72.1% concerned the differences in healthcare rules and regulations among countries or provinces⁶.

Not every society nowadays pays sufficient legal attention to telemedicine. Hong Kong and the Mainland China are no exception. For instance, Hong Kong has been developing telemedicine applications since 1996⁷. The Mainland China also conducted one of her earliest demonstration projects through teleconference between Beijing and Hong Kong in 1996⁸. No legislation has been enacted with regard to telemedicine practices in both territories. In Malaysia, the Telemedicine Act was enacted in 1997.

After the change of sovereignty in 1997, people movement between Hong Kong and the Mainland China has been tremendously rising⁹. It is not unusual that

⁶ PricewaterhouseCoopers conducted the survey. See Shelley Martin, "Public ignorant about telemedicine, survey finds" in *Canadian Medical Association Journal*, 3 April 2001, 164, 7.

⁷ Peter Ko, "Telemedicine in Hong Kong".

<<http://www2.telemedtoday.com/articles/telemedicinehongkong.shtml>> accessed 5 December 2005.

⁸ R. Hsieh, N.M. Hjelm, J.C.K Lee, and J.W. Aldis, *op.cit.*, p. 142.

⁹ According to the Census and Statistics Department of Hong Kong, the number of Hong Kong resident departure to the Mainland China was increasing from 61.1M in 2001 to 75.8M in 2006, while

people will go back to their respective territory of residence for healthcare services while they are working/living in the Mainland China/Hong Kong. More than that, there are always other cross-border demands for healthcare services. One example is the high demand of the pregnant ladies in the Mainland China for obstetric services in Hong Kong. The reasons behind such demands may be many-folds, but one cannot deny that these demands exist and telemedicine may help to some extent, if not all. There is therefore a need to examine the medico-legal liability of healthcare professionals and the rights of patients before cross-border telemedicine applications will be widely practised in Hong Kong and the Mainland China in the foreseeable future.

Purpose of this study

Purposes of this research are as follows:

- (a) To study the contemporary and global trend of the development of laws in telemedicine;
- (b) To identify foreign legal issues in telemedicine;
- (c) To study domestic laws relating to telemedicine applications in Hong Kong and the Mainland China;
- (d) To reflect and compare foreign legal issues of telemedicine in the context of Hong Kong and the Mainland China;
- (e) To assess the adequacy of existing laws in Hong Kong and the Mainland China in the context of telemedicine practices;
- (f) To identify conflicts in laws, if any, in Hong Kong and the Mainland China when telemedicine applications are to be practised in-between the two territories; and
- (g) To make recommendations to healthcare professionals, stakeholders concerned and patients about their liabilities and rights for offsite telemedicine applications in-between Hong Kong and the Mainland China.

Legal Research in Telemedicine**Request for documents***For the XXXX Hospital*

1. Your policy, guidelines, and protocols of telemedicine practices (both legal and non-legal)
2. Your policy and plan of buying, selling and allowing reimbursement of inside-territory/offsite telemedicine practices
3. Your policy, plan and rules regulating
 - (a) the establishment of e-health websites
 - (b) the dispatch of health information through the Internet
 - (c) the sales of drugs/medical supplies/dietary supplements on the Internet
4. Information and statistics on your Hospital's practising telemedicine, if any, including training
5. Any subject officer(s) overseeing telemedicine practices in your Hospital
6. Statistics in recent 10 years, if available:

(A) Number of patients:

- (1) receiving healthcare services in Hong Kong who are
 - (a) Hong Kong citizens and living/working in the Mainland China
 - (b) PRC* citizens living/working in Hong Kong
 - (c) PRC citizens living/working in the Mainland China
- (2) receiving healthcare services in the Mainland China who are
 - (a) Hong Kong citizens living/working in Hong Kong
 - (b) Hong Kong citizens living/working in the Mainland China
 - (c) PRC citizens living/working in Hong Kong

(B) Total non-eligible persons receiving healthcare services in Hong Kong/the Mainland China

7. Your policy, guidelines and/or protocols of:
- Maintaining privacy and confidentiality of patient data for both paper and electronic records
 - Observing copyrights in the use/updating of your official Internet website(s)
 - Using electronic communications including but not limited to emails, electronic documents, and encryption

* PRC: The People's Republic of China

28 April 2008

(Address)

Dear XXXX,

Legal Research in Telemedicine

Reference is made to my letter of 31 December 2007. Recognizing your extremely busy work schedule, I am sending you this friendly reminder in relation to my previous request for information on telemedicine. Your advice and input is invaluable to the success of the captioned study.

In case your reply has been incidentally clashed with this letter, please disregard this one. The undersigned is pleased to provide further information you may require (mobile phone: (852) XXXX; email address: XXXX).

I look forward to your favourable reply. Thank you for your time and advice.

Yours sincerely,

(Kar-wai TONG)