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FACULTY OF LAW

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E-HEALTH, SOCIAL MEDIA AND THE LAW IN SOUTH AFRICA

**Can ethical concerns in e-health practice
be addressed through regulation?**

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LLM BY COURSEWORK AND DISSERTATION

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Research dissertation/research paper presented for the approval of Senate in fulfilment of part of the requirements for the LLM degree in approved courses and a minor dissertation/research paper. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of LLM degree dissertations/research papers, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation/research paper conforms to those regulations.

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ABSTRACT

Advances in information communication technology over the past few years have provided an alternative method of health care delivery in the form of electronic health or e-health. With the rise of international awareness, greater consumerism, patient empowerment and the use of technology the way health care is provided and consequently, legal systems and regulations, are being challenged and undergoing reform.

Although increasing in popularity and of enormous benefit, e-health has created potential ethical and legal challenges to the regulators, both internationally and in South Africa. E-health provides an attractive solution to the provision and practice of medical services and advice within an increasingly technologically driven environment. A clear tension exists between the traditional approach to health care practice and the emerging practice of e-health. Despite these disparities and difficulties it is suggested that the growth and practice of health is unavoidable and e-health is in the process of establishing its rightful place within the existing health care system. Regulators will have to find innovative ways and a creative and forward-thinking response to address the challenges arising from e-health development.

The barriers to the practice of e-health today are no longer technological, but legal and ethical. This dissertation explores the various legal and ethical difficulties faced by health practitioners and patients alike in the application and practice of e-health. These include informed consent, the relationship between the doctor and patient, accuracy of online content, confidentiality, privacy, data security and licensure. The existing and proposed legislation in place in South Africa and internationally to potentially address these issues is discussed. The broader question that is posed is whether greater e-health regulation is required in a developing country such as South Africa and if so what the regulations should address.

It is suggested that a degree of legal flexibility is required to accommodate these challenges, making the 'one-size-fits-all' approach of standardising and harmonising international regulations and applying them to a South African context not entirely feasible. As technologies often precede the development of laws on how to use them, and this certainly appears to be the case with e-health regulation in South Africa, greater public accountability, more consultation and the introduction of workable solutions in the health care sector are called for.

ABBREVIATIONS AND ACRONYMS

AIDS	- Acquired Immune Deficiency Syndrome
ART	- Anti Retroviral Treatment
ATA	- American Telemedicine Association
DOH	- Department of Health
ECT	- Electronic Communications and Transactions Act 25 of 2002
EMS	- Emergency Medical Services
EPR	- Electronic Patient Record
EU	- European Union
HIV	- Human Immunodeficiency Virus
HPCSA	- Health Professions Council of South Africa
ICESR	- International Covenant on Economic and Social Rights
ICT	- Information and Communications Technology
IT	- Information Technology
LAN	- Local Area Network
MRC	- Medical Research Council
NESC	- National e-Health Steering Committee
NHC	- National Health Council
NHI	- National Health Insurance
NHIS/SA	- National Health Information System of South Africa
OECD	- Organisation for Economic Cooperation and Development
PAIA	- Promotion of Access to Information Act
POPI	- Protection of Personal Information Bill
SMS	- Short Message Service
UNCITRAL	- United Nations Commission on International Trade Law
UNESCO	- United Nations Educational, Scientific and Cultural Organization
WHA	- World Health Assembly
WHO	- World Health Organisation
WMA	- World Medical Association

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I. CHAPTER 1 : INTRODUCTION AND DEFINITIONS

*'Progress is impossible without change, and those who cannot change their minds cannot change anything.'*¹

George Bernard Shaw

(a) Introduction

In this thesis I consider the legal and ethical challenges raised by the growing prominence and popularity of the provision of e-health services by qualified practitioners, support groups and laypersons online. It canvasses these issues with a view to determining whether greater regulation in a developing country is in fact necessary and desirable. Although all challenges facing the implementation of e-health initiatives cannot be considered, the more significant ones are looked at. The issues flowing from e-health initiatives to be addressed are: the accuracy and reliability of online health content, the nature of the doctor-patient relationship and electronic contract, privacy, confidentiality and data protection of personal information, informed consent and licensing and regulation of health care practitioners. I then consider the legislative and regulatory position in South Africa and internationally and explore whether a new regulatory framework is needed. In the final chapter I identify possible alternatives and propose a way forward.

The thesis proceeds in 6 chapters. Chapter 1 defines the concepts of e-health, telemedicine, health care and social media. I also consider the nature and scope of e-health and the importance of e-health as an alternative health care service. I then describe the social media and e-health patterns and trends that are rapidly, emerging worldwide as well as online health care in developing countries. Chapter 2 describes the current e-health approaches and regulations in South Africa and internationally. In Chapter 3 the consequential legal challenges facing e-health practitioners, users and regulators is explored. These include both the user's rights as well as the obligations on e-health practitioners. I consider the user's right to privacy, confidentiality and data

¹Brainy Quote.com <<http://www.brainyquote.com/quotes/quotes/g/georgebern386923.html>> Accessed 24 January 2013.

protection, the nature of informed consent in an electronic environment and the establishment of the patient-doctor relationship and the duty of care in an e-health encounter. The formation of an electronic contract is considered as is licensing and accreditation. Chapter 4 sets out examples of e-health applications in place in South Africa and internationally. Chapter 5 questions whether greater regulation is necessary in a developing country and why e-health poses a challenge to regulators. I also question whether it is possible to regulate social media and online content and compare regulations internationally to the South African position. Finally, Chapter 6 considers recommendations and a possible way forward.

(b) Social media, e-health, telemedicine and cyber-medicine defined

(i) Social Media

Social media is defined by the Merriam Webster dictionary as ‘forms of electronic communication through which users create online communities to share information, ideas, personal messages, and other content’.² Social networking provides instant data sharing and includes Web 2.0 applications such as MySpace, Facebook, Twitter, YouTube, Wikipedia as well as online websites developed for the purpose of information sharing and interconnectivity.

Information technology communication platforms through which e-health may be practiced and which may be used to electronically transfer information include, amongst others, the telephone, radio, fax, e-mail, the Internet, videoconferencing and satellite-based communications.³

With the increased efficiency and acceleration of information transfer between information technology networks, the barriers to prompt and reliable exchanges of information, including health information and medical imagery, have been greatly eased. People can access information faster and more easily than was previously possible.

²Merriam-webster.com <<http://www.merriam-webster.com/dictionary>> accessed 12 January 2013.

³C Jack and M Mars ‘Telemedicine a need for ethical and legal guidelines in South Africa’ (2008) 50(2) *South African Family Practice* 60a at 60c-d.

The value of e-health lies not in the communication technology as such but in the ability to share medical information and expertise with others.⁴ Online health related resources range from medical information, electronic journals, databases, support groups, professional associations, non-governmental organisations, universities, research institutes, commercial companies and governmental agencies. The health care interaction itself may encompass preventative advice, diagnosis, management, treatment, support and/or education.

(ii) E-health

'Health care' is defined as '[t]he prevention, treatment, and management of illness and the presentation of mental and physical well being through the services offered by the medical and allied health professions'.⁵

As patients have wider access to medical resources, in fact to the very ones accessed by medical professionals, this has led to 'higher quality standards and evidence-based medicine'.⁶ Patient to patient interchanges have also increased in popularity and created a need to reconsider preventive medicine and health promotion.⁷

Although no universally accepted definition exists, e-health is generally considered a broader term encompassing all tele-health activities⁸ and is described by the World Health Organisation (WHO) as lying at the intersection of 'medical information, public health and business'.⁹

It is claimed by Eysenbach that 'everybody talks about e- health these days, but few people have come up with a clear definition of this comparatively new term. Barely in use before 1999, this term now seems to serve as a general buzzword, used to characterise ... virtually everything related to computers and medicine'.¹⁰

⁴Medical information and advice is one of the most sought and retrieved types of information on the Internet and is driven by a huge consumer demand for online medical resources. A 2013 report found that 35% percent of US adults say that they have gone online specifically search for a medical condition they or someone else might have.

⁵Medical-dictionary.com <<http://www.medical-dictionary.com>> accessed 20 December 2012.

⁶G Eysenbach E Ryoung Sa and TL Diepgen 'Shopping around the Internet today and tomorrow: towards the millennium of cybermedicine' (1999) 319 (7220) *BMJ* 1294 at 1295.

⁷Eysenbach Ryoung Sa and Diepgen op cit note 6 at 1295.

⁸A Le Roux 'Telemedicine: A South African legal perspective' (2008) (1) *TSAR* 99 at 100.

⁹World Health Organisation *WHA58.28 e-health* Geneva: WHO 2005.

¹⁰G Eysenbach 'What is e-health?' (2001) 3(2) *Journal of Medical Internet Research* e20.

What appears certain is that e-health alters the traditional health care experience for the patient. Access to the health care system is not necessarily through a primary care practitioner and a patient does not always progress through the health care system in a linear fashion. Examination, diagnosis, treatment and follow-up care involving the physical presence and personal interaction of the primary practitioner does not necessarily follow the traditional pre-defined course. This departure from the traditional thinking is perhaps particularly controversial as the ultimate responsibility for the patient's care is not clearly enough defined.

(iii) Telemedicine

Telemedicine has been applied in various forms since the early 1960's and has continued steadily to develop in scope and application.¹¹ The definition of telemedicine adopted by National Health Information System of South Africa (NHIS/SA) is as follows: '[t]he practice of medical care using interactive audio, visual and data communications; this includes medical care delivery, consultation, diagnosis and treatment, as well as education and the transfer of medical data'.¹²

Telemedicine refers to the use of telecommunications technology in the provision of health care and education that is carried out at a distance.¹³ It refers to interactions for medical services between a host and a remote site using communication technologies and describes a 'technique' for health care delivery rather than any one specific technology.¹⁴ Telemedicine may be provided in real time, interactively between the participants using videoconferencing or Skype, for instance, and may make use of ancillary technological diagnostic tools such as electronic stethoscopes.¹⁵

Telemedicine may be divided into either 'store-and-forward' telemedicine or 'face-to-face' telemedicine. 'Store-and-forward', or asynchronous telemedicine, is used for non-emergency situations where the e-health consultation is made within 24 – 48 hours. The patient's data and accompanying images or sound files (usually x-rays, CT scans or MRI), are transmitted by secure e-mail or website to a colleague-health

¹¹L Rannefeld 'The doctor will e-mail you now: Physicians' use of telemedicine to treat patients over the Internet' (2004) 19 (1) *Journal of Law and Health* 75 at 77.

¹²Available at <<http://www.doh.gov.za/programmes/tele/july01.html>>

¹³Rannefeld op cit note 11 at 77.

¹⁴Le Roux op cit note 8 at 101.

¹⁵M Mars 'Telepsychiatry in Africa – A way forward?' (2012) 15 *African Journal of Psychiatry* 215.

practitioner, who then reviews the data and provides a diagnosis, advice and/or health management plan.¹⁶ In face-to-face or synchronous or telemedicine, e-health consultations are interactive and occur in real time, using for example, video-conferencing, a two-way telephone conversation or Skype applications.¹⁷

(iv) Cyber-medicine

Cyber-medicine or ‘medicine in cyberspace’ is closely related to telemedicine¹⁸ and is described as ‘the science of applying internet and global networking technologies to medicine and public health, of studying the impact and implications of the internet, and of evaluating opportunities and the challenges for health care’.¹⁹

Although there are areas of overlap, telemedicine²⁰ focuses primarily on a more restricted exchange of clinical information between patient and doctor or between doctor and doctor, while cyber-medicine entails the dissemination of health information and advice between a doctor and patient via the Internet or other online platform with or without an established or ongoing doctor-patient relationship.²¹ This would usually involve an online platform such as an Internet website where a health care practitioner, or a group of practitioners, offer various medical services to users. Services would usually be restricted to the provision of health care²², advice, information and second opinions and the health practitioner and user/patient communicate online via e-mail, instant messaging or a real-time chat service. The practice of this form of e-health, although increasingly popular, is also the most controversial with questions regarding the quality of the care, misdiagnosis, misrepresentation, breaches of privacy and confidentiality and the potential abuse of online pharmaceutical drug prescriptions being of the most concern.²³

¹⁶Ibid.

¹⁷P Malindi and MTE Kahn Letter to the Editor ‘Rural Telemedicine in Africa’ (2005) 47(8) *South African Family Practice* 4.

¹⁸Rannefeld op cit note 11 at 77.

¹⁹Eysenbach Ryoung Sa and Diepgen op cit note 6 at 1294.

²⁰The literal meaning is ‘health care at a distance’.

²¹Le Roux op cit note 8 at 100.

²²Primary health care is defined as ‘the provision of integrated, accessible, health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of the family and the community.’ Cited in EE Westberg RA Miller ‘The basis for using the Internet to support the information needs of primary care’ (1999) 6 *JAMIA* 6.

²³C Erwell ‘Telemedicine: overcoming obstacles on the road to global health care’ (2003) *International Trade Law Journal* 68 at 69.

Whereas telemedicine is generally applied to ‘diagnostic and curative medicine’, cyber-medicine is applied to ‘preventive medicine and public health’.²⁴ Telemedicine is driven by a so-called ‘technological push’ while cyber-medicine is characterised largely by a ‘consumer pull’.²⁵

The terms ‘telemedicine’, ‘tele-health’, ‘online health’, ‘e-health’, ‘connected health’ and ‘cyber-medicine’ however are used inconsistently and somewhat interchangeably in the literature and, to a large extent, should be interpreted within the context within which they are used. What is constant however in the definitions of ‘telemedicine’, ‘e-health’ and ‘cyber-medicine’ is the use of electronic and communication technology within health care practice.

For ease of reference I have used the more general term of ‘e-health’ unless the terms ‘telemedicine’ or ‘cyber-medicine’ are more appropriate or warranted.

(c) Nature and scope of e-health

Increasingly, the future of health care services is being defined by new media social network tools like weblogs, instant messaging, video chat, online consultations and advice forums. Social networks are revolutionising and reengineering the way doctors and patients interact.²⁶

E-health encompasses a wide range of activities and may include:

- consumer health information (access to medical information and/or advice on preventative care, primary care and condition management by individuals or patients);
- prevention of disease (includes access to the latest news, articles and trends in health care and medically related matters as well as health and well-being promotion);

²⁴G Eysenbach ‘Towards ethical guidelines for dealing with unsolicited patient emails and giving teleadvice in the absence of a pre-existing patient-physician relationship systematic review and expert survey’ (2000) 2(1) *J Med Internet Res* e1 Available at < <http://www.jmir.org/2000/1/e1/>>

²⁵‘Technology push’ refers to the existence and availability of technology without defining user’s demands and does not necessarily lead to a widespread use of telemedicine applications and/or services. Customer or ‘demand pull’ on the other hand is a response to users’ demands and needs irrespective of existing or developing technology.

²⁶C Hawn ‘Take Two Aspirin And Tweet Me In The Morning: How Twitter, Facebook, And Other Social Media Are Reshaping Health care’ (2009) 28 (2) *Health Affairs* 361.

- remote patient monitoring (includes home-centered care supporting self-management of chronic diseases and personal management tools such as online disease management for example online health and tracking applications);
- online discussion and support groups;
- health management information (web-based surveillance systems, electronic disease registers, electronic district health information systems);
- continuing education of health professionals and patients;
- electronic health and medication records (enabling sharing of patient data between points of health care and/or pharmacies);
- m-health (use of mobile devices such as cell-phones to share information or provide advice);
- virtual health care, diagnosis and treatment, (health professionals co-operation via ICTs, online diagnose and treatment of limited, specific medical conditions and provision of primary health care);
- telemedicine (use of ICTs to provide health care at a distance);
- e-prescribing (electronic prescriptions are sent directly from the health care practitioner to the dispensary and remote dispensing);²⁷ and
- health research.

One should however differentiate between those who use health resources on technological platforms merely as 'users' for advice and support for general conditions, and those you seek specific treatment, care and second opinions and may be described as 'patients'. The notion of e-health however is steadily transforming 'patients' into 'users' and finally into 'consumers'.²⁸

(d) Why e-health is important: The need for health care alternatives

The purpose of e-health is to improve the health of people through the optimal use of information and communications technology. In addition to facilitating health care education, administration and research, the use of communication technology may be of benefit in improving access and convenience to health resources, reducing the cost

²⁷B Futter 'The naked patient' (2012) 79(9) *South African Pharmaceutical Journal* 64.

²⁸N Friederici, C Hullin and M Yamamichi 'm-Health' *ICD: maximising mobile* 2012 45. Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

of health care and increasing efficiency, enhancing the quality of health service delivery, improving primary care interventions and public health initiatives and addressing and improving the shortage of health professionals through partnership, collaboration and training. When fully utilised and integrated into a health care system e-health offers an extensive advantage.²⁹

Social media provides an efficient, convenient, cost effective and private means of obtaining medical information and health care advice and e-health offers enormous benefit in informed decision-making and greater participation of individuals in directing their own health care.

E-health has the added advantage of affording users immediacy and anonymity as well as a wealth of information and perspectives on numerous health related topics. With immediate access at any time of the day or night, the continuous updating and revision of information and the extensive range of content available, social media resources can be differentiated from other traditional forms of obtaining information.

To illustrate how popular e-health has become, an incredible 92% of users surveyed revealed, in a study conducted by Fox and Rainie³⁰ that the health information they found during their last online search was 'useful' with 81% saying 'they learned something new'.³¹ Of the 21 million users who said they were influenced by what they read 70% said 'the web information influenced their decision about how to treat an illness or condition', 50% said 'the web information led them to ask a doctor new questions or get a second opinion from another doctor' and 28% said 'the web information affected their decision about whether or not to visit a doctor'.³² The significance of such widespread popularity seems to indicate that people are becoming more empowered to actively gain access to alternative accessible forms of health care services.

What is interesting is that the anonymity offered by the Internet is viewed as beneficial in that it 'allows users to ask awkward, sensitive, or detailed questions without the risk of facing judgment, scrutiny, or stigma, and to do so at their

²⁹Rannefeld op cit note 11 at 78.

³⁰Research conducted by a United States national survey conducted by the Pew Research Center's Internet & American Life Project.

³¹S Fox and L Rainie 'The online health care revolution' Pew Internet & American Life Project: Online Report 2000 Available at <<http://www.pewinternet.org/Reports/2000/The-Online-Health-Care-Revolution/Summary.aspx>> Accessed 30 January 2013.

³²Ibid.

convenience'.³³ Additionally, users or patients are free to engage in a more participative health care model which, in turn, alleviates the difficulties of physical access to health care practitioners experienced by those in isolated or remote areas.

Although studies on telemedicine in South Africa have to a large extent centered on the 'technological feasibility, specialist clinical interest, implementation costs and estimated cost savings',³⁴ there is a clear socio-economic benefit to patients, that of, better quality care, greater participation,³⁵ cost effectiveness and accessibility.³⁵

(e) Global social media and emerging e-health patterns

With the advent of the information revolution and heightened accessibility to information technology, people are significantly turning to the social media to satisfy a variety of informational, communication and entertainment needs. E-commerce and e-transactions have become increasingly popular with people opting to perform previously face-face transactions and relationships online thereby using social media platforms as a practical means to assist them in their daily lives.

In line with the major advances in information communications technology over the past few years, and changing consumer behaviour, new avenues for innovative approaches to medical and health care access and treatment have developed. The Internet has been seen as an optimal way and a powerful tool for disseminating health information and health care to the public.³⁶

Moreover, health care emphasis has shifted to the prevention of disease and the promotion of wellness. The prolific number of medical and health care web sites, on-line databases, health care advice services and publications available on the Internet is testimony to the need for ongoing alternative sources of medical advice, support and treatment. A vast array of health information and advice is available freely online with support groups and medical organisations, for example, the Heart and Stroke Foundation South Africa³⁷ and Diabetes South Africa³⁸, providing information to

³³SR Cotten and SS Gupta 'Characteristics of online and offline health information seekers and factors that discriminate between them' (2004) 59 *Social Science & Medicine* at 1795.

³⁴PA Jennett *et al* "The socio-economic impact of telehealth: a systematic review" 2003 *Journal of Telemedicine and Telecare* 311-312 and Le Roux op cit note 8 at 102.

³⁵Le Roux op cit note 8 at 102.

³⁶Cotten and Gupta op cit note 33 at 1795.

³⁷Heart Foundation SA <www.heartfoundation.co.za>, Accessed 12 December 2012.

³⁸Diabetes SA <www.diabetessa.co.za> Accessed 12 December 2012.

online users on the causes, symptoms, treatments and preventative measures for various conditions.

Websites such as 'My health at Vanderbilt'³⁹ that allow patients to gain online access to their medical reports and patient records, billings information, appointment bookings and clinical laboratory reports have also increased in popularity.⁴⁰

In addition, social media provides the capacity for online users to make contact easily and effortlessly with other users with similar conditions. Numerous online anecdotal accounts of users experiences, knowledge as well as the management of their conditions are available in text, audio and video formats online, with users posting comments and creating various forums for discussion.

With medical websites currently well in excess of 100 000 and the number increasing daily there is a global awareness if not, something of a fascination, with medically related online content.⁴¹

The social media's popularity as a health resource does not appear to be slowing down. A 2010 Harris Poll survey revealed that an estimated 175 million people in the United States have used the Internet to search for health related information and that the number continues to increase. Frequency of use has also increased noticeably with 32% of people who look for health information online do so 'often'. The poll found that the percentage of people who have gone online to search for health information had increased noticeably to 88 %, with a staggering 81% having looked for health information online in the last month. Of those searching for information 17% had gone online to look for health information ten or more times in the last month with on average a person doing this about 6 times a month. Moreover 'very few' people reported being dissatisfied with their ability to find what they were looking for online and over half reported discussing information they found on the Internet with their doctors.⁴²

E-health is a worldwide phenomenon and growing steadily. A survey conducted in the United States in 2010 by the Deloitte Centre for Health Solutions

³⁹My health at Vanderbilt.com <<http://www.MyHealthAtVanderbilt.com>> Accessed 6 February 2013

⁴⁰AO Adesina KK Agbele K Kehinde R Februarie AP Abidoye and HO Nyongesa 'Ensuring the security and privacy of information in mobile health-care communication systems' (2011) 107 (9-10) *South African Journal of Science* 1.

⁴¹Harris Interactive 'Cyberchondriacs on the Rise?' July 2012 Available at <<http://www.harrisinteractive.com/vault/HI-Harris-Poll-Cyberchondriacs-2010-08-04.pdf>> Accessed 19 January 2013.

⁴²Ibid.

reported that patients frequently search for information pertaining to the diagnoses and treatment options for their conditions as well as doctor reviews, second opinions and hospital comparison data.⁴³ In addition, the number of health-related applications in Apple's online App Store increased from 4000 in February 2010 to more than 15 000 by September 2011, just 18 months later.⁴⁴

Likewise, a survey of asthma patients between the ages of 12 and 40 years old named text messaging, email, and Facebook as being used at least weekly by the majority of respondents (82%, 77%, and 65%, respectively). Email was cited as the most preferred method of electronic health information communication, with interest also being expressed in text messaging and Facebook. Myspace and Twitter received less interest. Interestingly, female and Black or Hispanic participants were found to more likely have an interest in the use of electronic media for asthma care.⁴⁵ This trend seems to mimic the increase in usage of m-health in those sectors of the population who were previously regarded as being separated by the 'digital divide'.^{46,47}

As this medium continues to grow in accessibility and popularity, a clearer understanding of the extent to which online health care is impacting people's lives, along with the scope and implications this will have on them is required.

In the words of George Bernard Shaw, '[s]cience never solves a problem without creating ten more'.⁴⁸ Clearly, the popularity of social media and the wide and largely unrestricted access it affords is not unencumbered by complication and challenge.

⁴³P Keckley and M Hoffmann 'Social Networks in Health Care: communication, collaboration and insights' 2010 *Deloitte Centre for Health Solutions: Washington, D.C.*

⁴⁴N Friederici, C Hullin and M Yamamichi 'm-Health' *ICD: maximising mobile* 2012 45 at 51 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

⁴⁵A T Baptist et al 'Social Media, Text Messaging and Email preferences of Asthma patients between 12 and 40 years old' (2011) 48(8) *J Asthma* 824 - 830 Available on Pubmed at <<http://www.ncbi.nlm.nih.gov/pubmed>> Accessed 5 January 2013.

⁴⁶UNICEF 'African Mobile Observatory 2011: Driving Economic and Social Development through Mobile Services' 2011 Available at <http://www.unicef.org/southafrica/SAF_resources_mobilegeneration.pdf> Accessed 6 February 2013.

⁴⁷The term 'digital divide' is described by the OECD glossary of statistical terms as the 'gap' between 'individuals households, businesses and geographic areas at different socio-economic levels with regard to both their opportunities to access information and communication technologies (ICTs) and to their use of the Internet for a wide variety of activities' Available at <<http://stats.oecd.org/glossary/detail.asp?ID=4719>> Accessed 6 February 2013.

⁴⁸Brainyquote.com <<http://www.brainyquote.com/quotes/quotes/g/georgebern386923.html>> accessed 12 January 2013.

(f) Online health care in developing countries

It has been suggested by Sarasohn-Kahn and cited in the WHO report that people in developing countries such as South Africa, Brazil, India, Mexico, and Russia have ‘a greater reliance on online health information because of the higher costs associated with seeing a medical professional face to face’.⁴⁹ Additional challenges facing developing countries are the chronic shortage of health care facilities and medical practitioners.

With the exception of the WHO websites (www.who.int), the most accessed health sites globally are based in the United States and include the WebMD, PubMed, Medicinenet.com, Medline Plus, Drugs.com, and Medscape.⁵⁰ People living in developing countries are accessing international websites more readily than local ones. An investigation into the access of medical websites in Sri Lanka found that only 64% were owned and/or controlled by a Sri Lankan citizen or a Sri Lankan organisation.⁵¹ Most users in developing countries are by-passing local sites in favour of United States based websites. This indicates that users may be comfortable that US based websites are more secure and that the content is more accurate.

While Internet access has long been the preserve of those who have the means to afford it, significantly lower rates of Internet use have been reported in youth in developing countries to date. However, with the explosion of Internet accessibility via mobile devices⁵² the face of Internet access has changed dramatically in the past few years.⁵³ It was found that 72% of 15 to 24 year olds reported having a cellular phone and readily used mobile technology.

In sub-Saharan Africa, few regional health care policies address e-health.⁵⁴ And yet, many challenges that exist in developing countries including a shortage of

⁴⁹WHO op cit note 9 at 19 and J Sarasohn-Kahn ‘Health citizens in emerging countries seek health information online even more than their peers in developed economies’ 2011 *Health Populi* Available at <<http://www.healthpopuli.com/2011/01/06/health-citizens-in-emerging-countries-seek-health-information-online-even-more-than-their-peers-in-developed-economies>> Accessed 18 January 2013.

⁵⁰Sarasohn-Kahn op cit note 49.

⁵¹M Kommalage and A Thabrew ‘Use of websites for disseminating health information in developing countries: an experience from Sri Lanka’ *Proceedings of the 2nd International Conference on Theory and Practice of Electronic Governance* 2nd International Conference on Theory and Practice of Electronic Governance 2008.

⁵²‘M-health’ refers to health care services provided via mobile cellular devices.

⁵³A 2012 report by UNICEF reveals that South Africa leads as one of the highest users of mobile technology and mobile social networking in Africa, and it is the leading innovator in Africa in social networking, micro-blogging and content creation. See UNICEF South African mobile generation – Study on South African young people on mobiles 2012.

⁵⁴M Mars and RE Scott ‘Global e-Health policy: A work in progress’ (2010) 29 2 *Health Affairs* 239.

health care resources, increased burden of disease, a large proportion of the population living in rural areas and a lack of education and primary health care⁵⁵ could potentially be addressed through e-health solutions.⁵⁶

A 2008 report issued by the South African Department of Health confirmed that while Africa carries 24% of the global disease burden, it only has a low 3% of the world's health practitioners.⁵⁷ With countries like France, America and the United Kingdom having 34, 24 and 27 doctors per 10 000 population respectively, countries in the African region have a reported 2 doctors per 10 000 population.⁵⁸ This is by far the lowest doctor to population ratio worldwide.

Illness and death in developing countries is often due to health conditions which are largely preventable and for which medical solutions are known and seemingly easily implemented.⁵⁹ Despite this, the health of those living in developing countries remains at risk where a disproportionately high burden of infectious diseases, escalating health care costs, unacceptably high levels of mother and child mortality and a continuing HIV/AIDS pandemic exist.⁶⁰ This is exacerbated by the general lack of and poor quality of health care services and the chronic shortage of health care professionals.^{61,62} Despite the dire need for sustainable and efficient health care services and the increased awareness that the Internet and various online technological platforms provide a beneficial solution, e-health has not been fully integrated and remains on the fringe of most mainstream health care systems.⁶³

⁵⁵M Mars and C Seebregts 'Country Case Study for eHealth: South Africa' 2008 Rockefeller Foundation Available at <<http://www.ehealth-connection.org/content/country-case-studies>> Accessed 23-01-2013

⁵⁶Mars and Scott op cit note 54 at 239.

⁵⁷Department of Health 2008 Available at <<http://www.doh.gov.za>> Accessed 12 January 2013

⁵⁸World Health Organisation. World Health Statistics 2012 Available at <http://www.who.int/gho/publications/world_health_statistics/EN_WHS2012_Full.pdf> Accessed 22 January 2013.

⁵⁹Death among children under 5 years old in Africa primarily include diarrhoea, measles, malaria, pneumonia and HIV/AIDS.

⁶⁰Le Roux op cit note 8 at 99.

⁶¹M Kekana B Mkhize P Noe 'The practice of telemedicine and challenges to the regulatory authorities.' (2010) 3(1) *South African Journal of Bioethics and Law* 33

⁶²Le Roux op cit note 8 at 99.

⁶³Ibid.

(g) Could e-health (and more particularly m-health) provide part of the solution?

With an estimated 6 billion people worldwide (which roughly translates to 75% of the world's population) using and having access to a mobile phone, mobile phones are the single most ubiquitous modern technology.⁶⁴ It is reported by the World Bank that in some developing countries, more people have access to mobile phones than to electricity or clean water.⁶⁵ Mobile phone applications are portals to an online world – a powerful tool in providing developing countries with more than just a voice but also empowering them to more informed decision-making and wider choice.⁶⁶ The significance of the mobile phone is no longer in the phone itself, but in the way in which it is used and the content and applications to which users gain access.⁶⁷

With the rapid expansion of mobile technology, South Africans living in urban and rural communities have been able to more fully access digital information through mobile and computer internet connectivity than ever before. Statistics South Africa found that among the population of approximately 50 million in South Africa there is an account of 100.48% mobile penetration that is, of people owning, renting and/or having access to a mobile cellular device.⁶⁸ As of September 2011, Africa had the second largest mobile market in the world with over 620 million mobile connections.⁶⁹ The developing world is described by a World Bank report as being 'more mobile' than the developed world.⁷⁰

When linked to the Internet and social network platforms, mobile telephone functionality extends beyond mere one-to-one voice communication and instant messaging.⁷¹ Mobile technology has enabled instant wireless connectivity and enabled users to communicate in real time, and gain access to Internet-based software

⁶⁴M Tomlinson MJ Rotheram-Borus L Swartz and AC Tsai 'Scaling Up mHealth: Where Is the Evidence?' (2013) 10 (2) *PLoS Med* Available at <<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001382>> Accessed 13 February 2013.

⁶⁵World Bank 'Information and communications for development: maximizing mobile' 2012 3 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

⁶⁶Ibid.

⁶⁷Ibid at 4.

⁶⁸ Statistics South Africa, Key Results 2001 Available at <<http://www.statssa.gov.za/census01/HTML/C2001publications.asp>> Accessed 14 December 2012.

⁶⁹reported in UNICEF 2012 5, 'African Mobile Observatory 2011: Driving Economic and Social Development through Mobile Services' 2011.

⁷⁰World Bank 'Information and communications for development: maximizing mobile' 2012 3 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

⁷¹E Edouard and L Edouard 'Application of information and communication technology for scaling up youth sexual and reproductive health' (2012) 16(2) *African Journal of Reproductive Health* 197.

applications, in a way that was not previously possible.⁷² Consequently, mobile e-health or m-health⁷³ is emerging as the new and rapidly expanding technology platform for transforming e-health.⁷⁴

The WHO has advocated the use of reduced cost information technology as a means of improving the quality of service delivery especially for primary health care.⁷⁵ M-health uses wireless technologies for instance Bluetooth, GSM/GPRS/3G, WiFi and WiMAX, to transmit e-health information and facilitate e-health services. These applications are accessed through devices such as mobile telephones, voice recorders, patient monitoring devices, Smartphones, personal digital assistants (PDAs), sensor gadgets, laptops or tablet computers.⁷⁶ Medical information and data are stored on memory sticks and memory storage cards which are regarded as m-health tools.⁷⁷

The technology for m-health holds enormous promise for the public and private health care sectors⁷⁸ alike in improving the access and delivery of health care services within remote or vulnerable populations, but also to an increasingly technologically driven consumer.⁷⁹ In addition to this, the entry level for m-health services is often lower than that of other e-health applications or traditional health care delivery methods making it that much more financially attractive to users.⁸⁰ The youth with their familiarity, adaptability and high usage of mobile phones and social networking can specifically benefit from m-health applications especially for instance in health promotion, disease prevention and sexual and reproductive health.⁸¹ The

⁷²Adesina et al op cit note 40 at 4.

⁷³'M-health' is defined as encompassing 'any use of mobile technology to address health care challenges such as access, quality, affordability, matching of resources, and behavioral norms [through] the exchange of information' in Friederici et al 'm-Health' ICD: maximising mobile 2012 45 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 10 February 2013.

⁷⁴ M Mars and C Jack 'Why is telemedicine a challenge to the regulators?' (2010) 3 (2) *SAJBL* 55 at 56.

⁷⁵ World Health Organisation *WHA58.28 e-health* Geneva WHO 2005.

⁷⁶Adesina et al op cit note 40 at 4.

⁷⁷R Wootton NG Patil et al, *Telehealth in the Developing World* 2009 Royal Society of Medicine Press Ltd 43 Available at <

http://www.ghdonline.org/uploads/Telehealth_in_the_Developing_World_2012_1.pdf> Accessed 10 February 2013.

⁷⁸The use of mobile phones for public health awareness on a wide scale has been recently demonstrated by the 'Text to Change' campaign for HIV/TB awareness in Uganda. Short messages stating 'If you have HIV, you might have TB. Get tested and get treated. TB is curable. Visit a nearby health centre for testing and treatment' and medicine adherence messages were sent to over 4000 people. Available at <<http://www.texttochange.org/blog/using-mobile-technology-tb-control-uganda>> Accessed 8 February 2013.

⁷⁹Adesina et al op cit note 40 at 4.

⁸⁰Friederici et al op cit note 28 at 50.

⁸¹Edouard and Edouard op cit note 71 at 197.

youth are skilled technological consumers and reproductive health programmes⁸² have indicated that youth involvement and participation, for instance in their ability to comment, blog or use the 'share button', in the application of e-health initiatives improves outreach and impact. It would seem that the interactivity and participatory functionality in e-health applications proves popular and highly desirable to the youth.⁸³ In light of this, Edouard suggests that it is feasible then that health care professionals become familiar with using social networking platforms such as Facebook and Twitter in enhancing their service delivery.⁸⁴

It is reasonable to speculate that developing countries have much to gain from leveraging off of expanding 3G networks and mobile broadband and that e-health applications are perfectly placed to provide a potential solution to the shortage of preventative and primary health care in South Africa.

⁸²The dissemination of information on sexual and reproductive health issues has been demonstrated in various projects across Africa. See Family Health International 'Mobile technology: text messages for better reproductive health' 2012 Available at <http://www.fhi360.org/en/Research/Projects/Progress/GTL/mobile_tech.htm> Accessed on 8 February 2013, in this regard.

⁸³Edouard and Edouard op cit note 71 at 197.

⁸⁴Ibid.

II. CHAPTER 2 : APPROACH AND REGULATORY FRAMEWORK

(a) E-health perspective and regulations in South Africa

The South African Minister of Health, Dr. Aaron Motsoaledi, identified e-health as a 'strategic imperative' and as one of the 'priorities' in the health system moving forward.¹ This ongoing commitment was reiterated in his address at the first South African Telemedicine Conference held in Cape Town in September 2010.² In line with this, the Department of Health has developed a national e-health Strategy for 2012 – 2016 with the aim of integrating e-health into the 'transformation and improvement of health care services in South Africa' and creating a 'single, harmonised and comprehensive e-health strategy'.³

There have been a large number of telemedicine initiatives over the past few years in South Africa particularly in rural communities, albeit with varying degrees of success.⁴ The intention has been to provide rural communities with access to the specialist expertise available in larger medical centres in South Africa.

As no separate health legislation exists for medical websites, where health care professionals provide health care or advice on the Internet or other technological platforms, they do so according to the general health legislation in force at the time.

Those who process health information are obliged to do so in accordance with the legislation relating to the processing of personal information.

As South Africa is a unique combination of elements of both a developed and a developing country, an enormous disparity exists between health care services and the health information systems in the private and public sectors. The duality of the South African health care system is most noticeable in relation to the resources, accessibility, affordability and quality of services available.⁵ To bridge this divide requires forward

¹A Telemedicine Strategy for South Africa 2010 - 2015 Extending Better Health care *Version 3 National e-health Steering Committee June, 2010* and Department of Health National e-health Strategy 1012-2016 8

²Speaking notes for Dr. A.P Motsoaledi for the 1st Southern African Telemedicine Conference 2010 Available at < <http://www.doh.gov.za/show.php?id=2104>> Accessed 8 February 2013

³Department of Health National e-health Strategy 1012-2016 8 Available at <http://www.doh.gov.za/docs/stratdocs/2012/eHealth_Strategy_South_Africa_2012-2016.pdf> accessed 9 February 2013.

⁴currently 86 public health care/telemedicine sites exist in South Africa, of which only 44% are active and functioning

⁵P Matshidze and L Hanmer 'Health Information Systems in the Private Sector' 2007 *South African Health Review* 89.

thinking and an innovative approach – an approach that is practical and achievable but also both legally and ethically sound. The following section discusses relevant constitutional and legislative provisions.

(i) The South African Constitution⁶

A. Constitutional right to health care

Two-thirds of the Constitutions worldwide have provisions relating to health and such provisions are almost always universally applicable, rather than limited to a particular group.⁷

South Africa is founded on constitutional supremacy and the rule of law.⁸ All legislation and regulations inconsistent with the Constitution are invalid. The Constitution promotes the advancement of human rights and freedoms for all people of South Africa. It provides a foundation for socio-economic rights including the right to the provision of health care services in Section 27(1)(a).

Section 27(1)(a) provides that '[e]veryone has the right to have access to health care services, including reproductive health care;'

Further, Section 27(2) of the Constitution places an obligation on the State to ensure the right of access to health care by providing that : 'the State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right of the people of South Africa to have access to health care services'.

Section 27(3) provides that 'no one may be refused emergency medical treatment'.

These sections not only entrench the right of the people of South Africa to have access to health-care services but mandate the State to perform in the provision of such health care. Consequently, the legislature, when making regulatory health care legislation⁹ and the executive, when making decisions regarding health care in South Africa, which would include provisions relating to e-health, are mandated to take into

⁶The Constitution of the Republic of South Africa Act 1996.

⁷ED Kinney and BA Clark 'Provisions for health and health care in the constitutions of the countries of the world' (204) 37 *Cornell International Law Journal* 285 at 291.

⁸s 1(c) *ibid.*

⁹s 8(1) *ibid.*

account the human rights of the people of South Africa and their unique and entrenched socio-economic rights and obligations.

Specifically, the Constitution includes not only the right of access to health care and to not be denied emergency medical treatment, but also gives effect to the right of all people to administrative action which is lawful, reasonable and procedurally fair.¹⁰ The implication of this is that the legislature (and other regulatory bodies) as well as the executive must apply their minds reasonably and fairly when considering whether e-health is permitted or denied in South Africa, thereby putting the human rights of the South African people foremost in its considerations regarding e-health regulatory measures.

Consequently, it is incumbent upon the State, including the Health Professions Council of South Africa (HPCSA) as a statutory body established pursuant to the Health Professions Act No. 56 of 1974, to take reasonable measures to achieve the progressive realisation of health care in South Africa and to adopt health care laws, regulations, guidelines and directives that are consistent with achieving the fulfilment and protection of the right to health care services.

This obligation is further emphasised in section 45(1) of the National Health Act where the Minister of Health is mandated to 'prioritise the health services that the state can provide taking into consideration health needs and resources available' and to 'prescribe mechanisms' to enable a 'coordinated relationship' between the private and public health care sectors in the delivery of health services.

B. Influence of international law in interpretation of constitutional rights

Further, Section 39(1) of the Constitution, on the interpretation of the Bill of Rights, provides '[w]hen interpreting the Bill of Rights, a court, tribunal or forum (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom; (b) must consider international law; and (c) may consider foreign law'.

This provision is unique to the South African Constitution and is the only one that expressly allows the courts to use extra-systemic information in interpreting the Bill of Rights. The South African courts are empowered to use foreign inferences in

¹⁰s 33 *ibid.*

interpreting national legislation and in resolving legal issues with regard to the rights protected in the Constitution. The court in fact, 'must' promote the 'values that underlie an open and democratic society', 'must' consider international law sources and 'may' consider foreign law in interpreting the Bill of Rights.

The courts are thus empowered to compare international constitutional law and to seek and borrow interpretive solutions from international jurisdictions and integrate them into the interpretation and application of South African law.¹¹

The court can therefore refer to international instruments to which South Africa is not a party and therefore not formally bound, such as the European Convention on Human Rights, International Covenant on Economic and Social Rights and the Inter-American Convention.

Section 231(4) of the Constitution provides that an international treaty will become law in South Africa when it is enacted into South African law by national legislation. and makes provision in Section 232 that '[c]ustomary international law is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament'.

(ii) South African legislation : the National Health Act No. 61 of 2003

The National Health Act has as its primary purpose to 'provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws...with regard to health services...!.

In the preamble to the National Health Act, the Act recognizes 'the socio-economic injustices, imbalances and inequities of health services of the past and the need to improve the quality of life of all citizens', and acknowledges section 27(2) of the Constitution which provides that the State must take 'reasonable legislative and other measures within its available resources to achieve the progressive realisation of the right of the people of South Africa to have access to health care services'.

It is the specific purpose of the National Health Act to 'unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa' as well as to 'promote a spirit of

¹¹A Lollini 'The South African Constitutional Court Experience: Reasoning Patterns Based on Foreign Law' (2012) 8 2 *Utrecht Law Review* 55 at 57.

co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans'.

With regard to e-health in South Africa, Chapter 2 has particular relevance. Sections 5 through 20 provide for the rights and duties of users and health care practitioners, section 7 provides for informed consent, section 14 for confidentiality and section 15 and 16 provides for access to health records. These sections serve to transform ethical principles, such as informed consent, into statutory requirements.¹²

(iii) South African regulatory guidelines

Previously, medical practitioners in South Africa relied primarily on ethical principles and guidelines as determined by the HPCSA, international codes of conduct and established ethical principles for guidance.¹³ The HPCSA, a statutory body and mandated by the State to provide regulations, has developed a series of ethical guidelines which have been set out in booklets and contained in regulations, for example, the good practice relating to 'Confidentiality: protecting and providing Information' and the proposed guidelines on ethical values contained in a booklet on Tele-medicine.¹⁴

Certainly, one shouldn't distinguish between e-health practitioners per se and other health care practitioners but rather talk of health care practitioners who use e-health mechanisms and platforms and who must nevertheless adhere to the same law and regulations because all that is needed is clinical processes and procedures to limit risk. Health care practitioners who practice e-health have the same responsibilities and duties required by them being qualified and registered in their respective professions. These duties are outlined in the HPCSA's general ethical guidelines for health care professionals.

¹²H Oosthuizen T Verschoor, T 'Ethical principles becoming statutory requirements' (2008) 50 (5) *SA Family Practice* 36 at 38.

¹³Although still regarded as primary sources of guidance, the promulgation of recent legislation has changed this considerably. See H Oosthuizen T Verschoor, T 'Ethical principles becoming statutory requirements' (2008) 50 (5) *SA Family Practice* 36 at 37-40.

¹⁴Second Edition, Booklet 11, Pretoria, May 2007 and the 'General Ethical Guidelines for Good Practice in Telemedicine' Discussion document of the Human Rights, Ethics and Professional Practice Committee of the HPCSA. Available as minutes from the HPCSA secretary at <<http://www.hpcsa.co.za>>

The HPCSA defines telemedicine as 'the exchange of information on health care at a distance for the purpose of facilitating, improving and enhancing clinical, educational and scientific health care and research, particularly to the under-served areas in the Republic of South Africa'. The HPCSA recommends that patient-initiated tele-consultation be restricted to situations in which a previous health care professional-patient relationship existed for the same or a related health condition.¹⁵ The HPCSA's proposed definition of telemedicine is restrictive and deeply problematic.

South Africa's position regarding the legal regulation of e-health is somewhat delicate. Regulations have not as yet addressed or solved any of the problems or challenges facing e-health in this country, thereby leaving South Africa vulnerable to many potential dangers but also to missed opportunities. The law needs to keep ahead of development in e-health, not behind it, in order to avert unnecessary commercial and humanitarian uncertainty and compromise. It is surely not appropriate to leave the issues to be determined by the courts only if and when conflicts arise. A too little, too late, approach cannot be desirable and should be avoided at all costs. Similarly a blanket denial or avoidance of the inevitable emergence of new e-health platforms is of little help either. What is required of South African policymakers is to carefully balance competing interests in a forward-thinking way, by embracing the principles already in its very foundations – openness, democracy, human dignity, equality and freedom – to create a sound legal framework regulating e-health.

(b) International approaches to e-health and regulations

Health care is one of the biggest industries in the United States in terms of size and scope, and yet the health care sector has been 'among the slowest and most reluctant to embrace progress in communications and information technology'.¹⁶ Internationally, the drafting of e-health regulations and policy-making has been primarily the domain of professional organisations, health institutions and/or the state authorities.

¹⁵M Kekana B Mkhize P Noe 'The practice of telemedicine and challenges to the regulatory authorities.' (2010) 3(1) *South African Journal of Bioethics and Law* 33 at 34.

¹⁶C Hawn 'Take Two Aspirin And Tweet Me In The Morning: How Twitter, Facebook, And Other Social Media Are Reshaping Health care' (2009) 28 2 *Health Affairs* 361 at 362.

E-health is essentially borderless and as such requires regulation to facilitate data transference and user mobility.¹⁷ As the nature of e-health is such that it flows freely across borders of countries, it would seem imperative that a process of continued consultation and engagement be embarked upon - this however is not often the case.¹⁸ Fundamental disparities in different jurisdictions exist regarding e-health legislation and infrastructure, with laws and regulations usually defined at a high level of abstraction. There is as yet no consistently defined codex of medical ethics across jurisdictions.¹⁹ Despite this, international acknowledgement and progress with regard to e-health has been forthcoming and the foundations established to encourage its realisation.

(i) International treaties

UN Universal Declaration of Human Rights : 1948

The human right to health is recognised in international instruments most notably, in article 25(1) of the Universal Declaration of Human Rights. Article 25(1) affirms that '[e]veryone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services'.²⁰

International Covenant on Economic and Social Rights (ICESR) : 1985

Article 12(1) of the International Covenant on Economic, Social and Cultural Rights provides a right to health. Under Article 12 of the ICESR '[e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity'. Article 12(2) provides 'steps to be taken by the States parties ... to achieve the full realisation of this right'.²¹

¹⁷M Mars and RE Scott 'Global e-Health policy: A work in progress' (2010) 29 2 *Health Affairs* 239.

¹⁸C Jack and M Mars 'Telemedicine a need for ethical and legal guidelines in South Africa' (2008) 50(2) *South African Family Practice* 60a at 60b.

¹⁹Z Stapić N Vrček and G Hajdin 'Legislative Framework for Telemedicine' University of Zagreb, Croatia Available at <<http://www.ceciis.foi.hr/app/index.php/ceciis/2008/paper/view/74/90>> Accessed 8 February 2013.

²⁰Available at <<http://www.un.org/en/documents/udhr/index.shtml#a25>> Accessed 30 January 2013.

²¹Office of the High Commissioner for Human Rights CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12).

The International Covenant on Economic and Social Rights Committee (ICESR) obliges state parties' to satisfy minimum essential levels of the rights contained in the ICESR. This includes the right to primary health care.

To assist in the implementation of the ICESR, General Comment no 14²² describes the 'interrelated and essential elements' and obligations with regard to the 'realisation of the right to health'. It notes that the core obligations such as access without discrimination to health facilities, goods and services should be 'culturally acceptable', appropriate and made available to all especially to vulnerable or marginalised groups. It notes that accessibility includes 'the right to seek, receive and impart information and ideas concerning health issues' as provided for in article 19.2 of the ICESR. And goes on to state that 'accessibility of information should not impair the right to have personal health data treated with confidentiality'.²³

Universal Declaration on Bioethics and Human Rights : 2005

The Universal Declaration on Bioethics and Human Rights was adopted by the United Nations Educational, Scientific and Cultural Organisation (UNESCO) at the 33rd session of the General Assembly Conference in October 2005. It affirms that 'ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedom'.²⁴

The declaration acknowledges developments in society brought about by scientific and technological changes that are now being practice across the borders of countries.²⁵ It serves to identify and reconcile science and technological advancements with ethical values, freedom and human dignity by providing guidelines for scientific and technological developments which includes the practice of e-health.²⁶

The World Health Organisation Resolution on e-Health : 2005, 2007

²²Adopted at the twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 and contained in Document E/C.12/2000/4.

²³Office of the High Commissioner for Human Rights CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)

²⁴ UNESCO 2007 Available at <<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/>> Accessed 30 January 2013.

²⁵Kekana et al op cit note 15 at 33.

²⁶Ibid.

The World Health Organisation declared that the achievable objective of ‘e-health for all in 2015’ is both credible and realistic to realise the broader 2015 United Nations Millennium Development Goals in health, education, employment and poverty reduction.

At the fifty-eighth session of the World Health Assembly in May 2005, Resolution WHA 58.28 on e-health was adopted. The resolution notes the impact that ‘advances in information and communication technologies could have on health-care delivery, public health, research and health-related activities for the benefit of both low- and high-income countries’.²⁷ It therefore urges member states ‘to draw up long-term strategic plans for developing and implementing e-health services in the various areas of the health sector that includes an appropriate legal framework and infrastructure and encourages public and private partnerships’.²⁸

The 2005 WHO resolution fails to resolve legal and ethical questions related to e-health, more notably the issues surrounding the lack of direct patient-practitioner contact, informed consent, confidentiality, data integrity and security and the legal implications of cross-border e-health practice.²⁹ Although the resolution specifically encourages member states ‘to reach communities, including vulnerable groups, with e-health services appropriate to their needs’³⁰ it neglects to address the ethical issues surrounding standard of care with regard to vulnerable communities in any meaningful way.³¹

The 2007 World Health Organisation Resolution on health technologies, WHA60.29 seems to fare no better with regard to addressing ethical issues. Rather its focus is on setting a framework within which health technologies can exist thus enabling the achievement of the WHO health-related Millennium Development Goals.³² It encourages member states ‘to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement

²⁷WHO resolution WHA 58.28 121 Available at <http://apps.who.int/iris/bitstream/10665/20378/1/WHA58_28-en.pdf> Accessed 13 January 2013.

²⁸Ibid.

²⁹Jack and Mars op cit note 18 at 60a.

³⁰WHO resolution WHA 58.28 op cit note 27.

³¹Jack and Mars op cit note 18 at 60a.

³²WHO resolution WHA 58.28 op cit note 27.

and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment'.³³

According to the 2007 WHO resolution 'the most favorable approach to the implementation of e-health at the national level is to have a framework of strategic plans and policies which lay the foundations for development.' It is envisaged by the resolution that strategies and regulations be put in place by member states to safeguard citizens, while promoting equity, observing cultural issues, ensuring interoperability and maximising accessibility to e-health solutions. Strategies for collaborative approaches to e-health policy or their implementation are however not mentioned in the 2007 resolution.

Following the formation of the WHO's e-health strategy, the WHO established the Global Observatory for e-health. The intention was to conduct a global e-health survey designed to explore the status of e-health applications and solutions. The resultant report WHO 'Telemedicine – Opportunities and developments in Member States' was published in 2010 and sets out 'information and guidance on best practices, policies, and standards in e-health'.³⁴

(ii) European Union legislative position

While it would be impossible to address the legislative debates around all issues in e-health consideration is only given to the EU directives and OECD guidelines.

The European Union has made a clear commitment to the provision and improvement of public health. Under article 152 of the European Community Treaty member states have the primary responsibility for the organisation and delivery of health services.³⁵ The article provides that all EU policies and activities should 'complement national policies', and should be directed towards 'improving public health, preventing human illness and diseases, and obviating sources of danger to human health'. Activities and policies should endeavour to 'fight against the major

³³WHO resolution WHA 58.28 op cit note 27.

³⁴WHO 'Telemedicine – Opportunities and developments in Member States' Global Observatory for e-Health series vol 2 2010 Available at <http://www.who.int/goe/publications/goe_telemedicine_2010.pdf> Accessed 1 February 2013.

³⁵The role of the EU in this regard is one of complementing national law policies rather than one of establishing public health programmes. See J Lear E Mossialos 'EU law and health policy in Europe' (2008) 10(3) *Euro Observer* 1-3.

health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education'.³⁶

The EU recognises in its Framework Programme for Horizon 2020 - Research and Innovation for 2014 -2020³⁷ that needs of specific populations are better addressed 'in an integrated manner', and proposes the 'development of stratified and/or personalised medicine' in 'providing assisted and independent living solutions'. In this document the EU aims to improve 'health promotion and disease prevention' and to foster 'individual empowerment for self-management of health.' Its purpose is to maximise legal clarity pertaining to the effective sharing of information using existing and future national legislative frameworks relevant to e-health and to the development and adoption of national enabling legislation to allow e-health to be used more effectively. The development of innovative technology and its application in health care practice, notably e-health, is supported.

The European Commission proposed an EU directive setting out rules for receiving cross-border health care and for the reimbursement of these costs. The Directive was formally adopted in Brussels by the European Parliament and the Council in 2011 and provides clarity on who is responsible for quality and safety of care in cross-border settings. It also seeks to strengthen cooperation between member states.³⁸

European legislative position regarding data privacy, the extent of privacy rights and data protection regulations vary under different legal regimes.³⁹ European Union member states are required to enact national privacy legislation to comply with the European Union Data Protection Directive.⁴⁰ The object of the Directive, which came into force in 1998, is to protect the privacy of individuals and thereby adequately facilitate the freedom of movement of data across the European Union.

The European Data Protective Directive sets out principles of data processing and creates uniformity in the processing of personal information across member states.

³⁶EU Treaty Available at <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E152:EN:HTML>> Accessed 30 January 2013.

³⁷Regulation of the European Parliament and of the Council Available at <[http://ec.europa.eu/research/horizon2020/pdf/proposals/com\(2011\)_809_final.pdf](http://ec.europa.eu/research/horizon2020/pdf/proposals/com(2011)_809_final.pdf)> Accessed 30 January 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

³⁸EU Directive on cross-border health care Directive 2011/24/EU

³⁹Stapić et al op cit note 19.

⁴⁰EU Data Protection Directive 95/46/EC Available at <http://ec.europa.eu/justice_home/fsj/privacy/> Accessed 10 January 2013.

It grants control over the collection, transmission, or use of personal information by data subjects (the person to whom the personal data relates) and provides data subjects with the right to be notified of all uses of the data and explicit consent must be obtained from the data subject prior to the collection of data on race/ethnicity, political opinions, union membership, physical/mental health, sex life, and criminal records.

Moreover the Data Protection Directive requires that personal information be protected by adequate security, with sensitive data, such as health data requiring an even stricter measure of protection. Data subjects have the right to obtain copies of information collected as well as the right to correct or remove personal data.

Importantly, personal data may not be transferred to other countries or member states within the EU without assurance of an ‘adequate level of protection.’ Although the European Union Data Protection Directive establishes a regulatory framework for the free movement of personal data, it prohibits the transfer of personal information of Europeans to countries not having a minimum level of protection. Article 25(1) provides that ‘members must prohibit the transfer of personal data to non-member states which do not ensure an adequate level of data protection’.

Additionally, the OECD Guidelines on the Protection of Privacy and Trans-border Flows of Personal Data⁴¹ sought to harmonise national privacy legislation amongst OECD member states and uphold the right to privacy and data protection while safeguarding interruptions in international flows of data.⁴²

(iii) International Ethical Codes

The WHO has called for a ‘more holistic approach’ to be developed and implemented globally across the e-health spectrum.⁴³ Guidelines and regulations on medical content and health care advice as well as codes of ethics are recommended thereby ensuring content provider accountability and credibility. The approach proposed is the so-called ‘dot health top-level domain (TLD)’. A dot health TLD, it is suggested, would serve as an organisational indicator for quality health information sources on the Internet and go some way to addressing the problem of online health misinformation.

⁴¹adopted September 1980.

⁴²Article 2 of Part 1 ‘General Definitions’.

⁴³WHO resolution 2011 op cit note 27 at 7.

Despite questions being addressed on an international level, in certain cases it is almost impossible or inappropriate to provide solutions in a standardised manner, in which case, countries are required to regulate themselves in terms of their national law.

The World Medical Association (WMA) presented a statement in 2011 on the Professional and Ethical use of the Social Media the objectives of which were to consider the challenges relating to the use of the social media by health care professionals and patients and to provide a framework which would protect their respective interests while ensuring high professional and ethical standards.⁴⁴

The statement, while acknowledging the positive contribution that the Internet and other social media can offer, raised areas that required special consideration.

These include sensitive content, photographs and other personal material that is posted on social media forums that often exist in the public domain and have the capacity to remain on the Internet permanently. Although it is acknowledged in the Statement that patient portal, blogs and tweets are not a substitute for one-on-one consultation with physicians, it is accepted that they may 'widen engagement with health care services amongst certain groups'.⁴⁵

The Statement sets out various recommendations and calls on its member associations to create guidelines and address issues pertaining to the provision of health care using the social media.

The guidelines pertaining to health care in the social media context include *inter alia* 'to maintain appropriate boundaries of the patient-physician relationship in accordance with professional ethical guidelines just as they would in any other context', 'to study carefully and understand the privacy provisions of social networking sites, bearing in mind their limitations', and to 'ensure that no identifiable patient information be posted in any social media by their physician'.

In light of the adopted WMA Statement a white paper has subsequently been released⁴⁶ which more closely examines the role of the social media in the provision of health care and various ethical issues relating thereto.

⁴⁴World Medical Association Statement on the Professional and Ethical Use of Social Media. Adopted by the 62nd WMA General Assembly, Montevideo, Uruguay, October 2011 and Available at <<http://www.wma.net/en/30publications/10policies/s11/>> Accessed 10 December 2012.

⁴⁵Ibid.

⁴⁶September 2012.

III. CHAPTER 3 : CHALLENGES FACING E-HEALTH INITIATIVES

Although there are numerous advantages to e-health initiatives, the regulation of the practice of e-health proves something of a challenge to the regulatory authorities. This chapter considers the legal and ethical dilemmas most likely to be of concern to the regulators and provides a clearer understanding of the challenges facing e-health implementation.

Broadly, issues flowing from e-health initiatives and which should be addressed are (a) content quality and accuracy (b) the nature of the doctor-patient relationship and electronic contract, (c) privacy, confidentiality and data protection of personal information (d) informed consent and (5) licensing and regulation. Each of these is discussed in turn below.

(a) Content quality and accuracy

A growing concern is the quality, reliability and accuracy of information available online and the credibility of the persons providing such information. Inaccurate, misleading and dangerous information has the potential to cause harm with those users lacking evaluating skills at higher risk.

In its 2011 report the WHO identified safety and security of content on the Internet as a primary concern.¹ This would include the quality and reliability of online health information on the Internet. The WHO advised its member states to encourage the voluntary compliance by content providers and web site owners with quality control mechanisms such as government-based educational programmes, the use of appropriate technological content filters and controls, and by obtaining official seals of approval.² In so doing a standard may be created which, it is envisaged, will provide

¹WHO 'Safety and security on the Internet: challenges and advances in Member States' in *Global Global Observatory for eHealth Series*, v. 4 2011 56 at 57 Available at <http://www.who.int/goe/publications/ehealth_series_vol4/> Accessed 27 January 2013.

²For example, HONcode, provided by the Health on the Net Foundation, a non-governmental organisation providing certification of health care and information content providers and website owners. Its purpose is to ensure and endorse the dissemination of quality, objective and transparent health information. Since its inception, HONcode has reportedly been used by over 100 countries and covers 10 million web pages. Available at <<http://www.hon.ch/HONcode/>> Accessed 25 January 2013.

greater guarantees of credibility, objectivity and quality of the information and advice provided online.

Due to the lack of regulation in this regard, users may be at an increased risk of selecting content off of ‘official looking’ web sites that may lack peer review.³ Users have been reported as saying that in assessing the credibility of a website they primarily look at the professional design of the website.⁴ That users are influenced by the overall presentation of the content, and use this as criteria to determine the reliability of the information when no other means to verify the contents’ accuracy exists, is problematic.

Participative online forums such as, online discussion and support groups, attract users for their convenience, anonymity, cost-effectiveness, emotional support and exposure to extensive opinions, expertise and experience. A 2000 study found that users rated online support groups ‘more helpful’ than physicians.⁵

Despite their popularity, online discussion and support groups have been implicated as the primary culprits in the dissemination of misleading information, as much of the information provided is based on anecdotal or personal experience which may lack the critical perspective or credibility of health professions. Although a huge volume of users rely on online content, little is being done to control content or ensure accurate reporting.⁶

As the WHO report states the implications of erroneous or misleading medical content may be ‘particularly dangerous if acted upon unquestioningly’. Thus it is necessary to educate users on how to critically evaluate health content, thereby allowing them to make more empowered and better-informed decisions concerning the health content.⁷

Research has indicated that those who more frequently use social media services are not only better able to discriminate between useful and non-useful

³SR Cotten and SS Gupta ‘Characteristics of online and offline health information seekers and factors that discriminate between them’ (2004) 59 *Social Science & Medicine* 1795.

⁴G Eysenbach and C Kohler ‘How do consumers search for and appraise health information on the World Wide Web? Qualitative study using focus groups, usability tests, and in-depth interviews’ (2002) 324 (7337) *BMJ* 573 at 574.

⁵DA Grandinetti ‘Doctors and the Web: help your patients surf the Net safely’ (2000) 4 *Medical Economics* 28. However the loss of personal touch, the possibility of depersonalisation, and the potential for virtual visits replacing actual visits are considered concerning. See KE Edison DA Fleming, H Pak ‘Telehealth ethics’ (2009) 15 (8) *Telemedicine and e-health* 797.

⁶RJW Cline and KM Haynes ‘Consumer health information seeking on the Internet: the state of the art’ (2001) 16 (6) *Health Education Research* 671 at 673.

⁷WHO *Global Global Observatory for eHealth Series* op cit note 1 at 56-57.

information, but can do so more efficiently and are for the most part, satisfied with the information sought.⁸ Interestingly, it emerged that very few participants had ‘noticed and remembered which websites they had retrieved information from’ and ‘no participants checked any “about us” sections of websites, disclaimers or disclosure statements’ or ‘find out who the authors or owners of the website are’.⁹

As the Internet is largely unregulated it is currently incumbent upon the website owner or content provider to self-regulate in matters of content accuracy and quality with limited or no policing by the authorities.

(b) Right to privacy, confidentiality and data protection

Privacy, confidentiality and anonymity are significant concerns for users seeking online health information and care.¹⁰ A United States study found that 80% of users find it important that they can get health information anonymously, while 16% of users said they use the web to get information about a ‘sensitive health topic that is difficult to talk about’.¹¹¹²

Privacy is an enormous concern for users with many fearful that Internet tracking may reveal their searches or that third parties, such as their employers, may become privy to this information.¹³ Once a website has been accessed, a user’s ‘digital footprint’ may still be left behind. In line with their concerns an overwhelming majority, 81% of United States users in the study believe that health or medical companies should be sued if confidential information about them is disclosed without their consent.¹⁴

Data security is imperative in any e-health initiative and the elements of confidentiality, integrity and availability require greater exploration.

(i) Confidentiality : right to privacy

⁸Eysenbach and Kohler op cit note 4 at 575.

⁹Ibid. at 576.

¹⁰S Fox and L Rainie ‘The online health care revolution’ Pew Internet & American Life Project: Online Report 2000 Available at <<http://www.pewinternet.org/Reports/2000/The-Online-Health-Care-Revolution/Summary.aspx>> Accessed 30 January 2013 and Edison et al op cit note 5 at 797.

¹¹Interestingly, the most searched for health-related topic in 2011 was for information on chlamydia, a sexually transmitted disease, thus suggesting that the privacy and anonymity offered by online access to medical information is important to users.

¹²Fox and Rainie op cit note 10.

¹³Ibid.

¹⁴Ibid.

Information about a person's health is highly sensitive and therefore considered deserving of the strongest protection under the law.¹⁵ Health care practitioners have a legal and ethical responsibility to maintain patient confidentiality and privacy, including the integrity of a patient's data.¹⁶ The protection of confidentiality and privacy is described in the long-standing ethical principle of non-maleficence or *primum non nocere*, that is firstly, to do no harm.¹⁷

Online environments present an interesting challenge as the security and privacy requirements differ from those in traditional health care encounters.¹⁸ As information in an online environment is largely durable and easily distributable, ones 'digital footprint' has potential permanence and accessibility in cyberspace. The implications of misplaced or 'lost' information may thus be enormous.¹⁹ Consequently, the inappropriate use of social media may cause considerable harm to users by breaching confidentiality and violating patients' rights to privacy and data integrity.

Although established principles for health care professionalism exist these principles should be extended and adapted to online activity.²⁰ The social media, under the guise of anonymity, may appear to detach the consequences of certain online interactions. However, the health care practitioner will not escape liability for a violation of a person's rights, such as, disclosure of confidential pictures of patients by virtue of the fact that it was done remotely or anonymously. This is especially true of online interactions as they have potentially a far wider reach than typically face-to-face interactions.²¹

¹⁵AO Adesina KK Agbele K Kehinde R Februarie AP Abidoye and HO Nyongesa 'Ensuring the security and privacy of information in mobile health-care communication systems' (2011) 107 (9-10) *South African Journal of Science* 1 and H Oosthuizen T Verschoor, T 'Ethical principles becoming statutory requirements' (2008) 50 (5) *SA Family Practice* 36 at 38.

¹⁶The Hippocratic Oath, speaks of '[w]hatever, in connection with my professional service or not in connection with it, I see or hear in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret'.

¹⁷TL Beauchamp and JF Childress *Principles of Biomedical Ethics* 5th ed New York: Oxford University Press 2001 128.

¹⁸M Kekana B Mkhize and P Noe 'The practice of telemedicine and challenges to the regulatory authorities.' (2010) 3(1) *South African Journal of Bioethics and Law* 33 at 35

¹⁹SJ Mansfield SG Morrison HO Stephens MA Bonning SH Wang AH Withers RC Oliver and AW Perry 'Social Media and the medical profession' (2011) 194 12 *Med J Australia* 642 at 643-644.

²⁰SR Greysen T Kind and KC Chretien 'Online professionalism and the mirror of social media' (2010) 25 (11) *J Gen Intern Med* 1227-1229.

²¹Ibid.

Privacy and confidentiality is essential in any relationship between a health care practitioner and their patient, and e-health interactions are by no means an exception. Without the necessary assurances about data confidentiality and integrity users may be reluctant to divulge the information needed to practice good health care. Considerations include where, when and how data is stored, who and on what basis data may be accessed and what security measures are in place to safeguard data during storage and transmission.²²

The right to privacy is well established in international instruments such as the United Nations Declaration on Human Rights²³, the World Medical Association Declaration of Geneva of 1948, the international code of Medical Ethics of 1949 and the 1995 European Union Data Protection Directive²⁴, as well as in various international codes of practice. The United Nations guidelines urge member states to enact legislation that will 'accord personal information an appropriate measure of protection' and to 'ensure that such information is collected only for appropriate purposes and by appropriate means'.²⁵ Similarly the EU Data Protection Directive provides protection for EU citizens of personal data within the European Union. The directive states that the flow of personal data can be only within the boundaries of the member states where 'an adequate level of protection' can be guaranteed.

The protection of privacy is highly valued in South Africa. Fundamental to its protection is its inclusion in section 14 of the Constitution which provides that every person has the right to privacy, which includes the right to have his or her information kept confidential.

In South Africa various legislative provisions offer protection of personal health information. These provisions ensure that the confidentiality of personal health information is maintained at all times by those working in the public and private health care sectors.

Section 14 of the National Health Act states that 'all information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential'. The National Health Act places an obligation on

²²Adesina et al op cit note 15 at 1 and Oosthuizen and Verschoor op cit note 15 at 38.

²³United Nations Universal Declaration of Human Rights UN General Assembly 10 December 1948

²⁴European Union Data Protection Directive 95/46/EC.

²⁵Adesina et al op cit note 15 at 1.

health care practitioners to protect personal information about their patients and must ensure that patient information is protected against improper disclosure.²⁶

In addition to various legislative provisions, health care practitioners are bound by the legislative provisions and ethical rules of the regulatory authorities governing their respective professions.

In South Africa the HPCSA sets out guidelines on good medical practice and codes of ethics for its members.²⁷ The HPCSA imposes guidelines relating to the storage, confidentiality and protection of patient information. The Ethical Rules of the HPCSA state that a practitioner may divulge information regarding a patient only if this is done: 'in terms of a statutory provision, at the instruction of a court, in the public interest, with the express consent of the patient, with the written consent of a parent or guardian of a minor under the age of 12 years, or in the case of a deceased patient with the written consent of the next of kin or the executor of the deceased's estate'.²⁸

In terms of paragraph 4 of the HPCSA ethical rules 'where health care practitioners are asked to provide information about patients, they should seek the consent of patients to disclosure of information wherever possible, whether or not the patients can be identified from the disclosure...anonymise data where unidentifiable data will serve the purpose; and keep disclosures to the minimum necessary'.²⁹

It is recommended by Matshidze and Hanmer that a review of health information systems policy, legislation and practice should be put in place as to date no formal, integrated health information system supporting patient care across the private health care sector exists in South Africa.³⁰ It is further suggested that a standards body dedicated to the national health information standards be established to co-ordinate the public and private health information systems and to ensure the confidentiality of patient data.

²⁶The confidentiality of a patient's health record is protected in sections 12, 13, 14, 15, 16 and 17 of the National Health Act as read together with the definitions of 'personal information' in section 1 of the Promotion of Access to Information Act. Section 17 specifically protects health records and imposes sanctions for any limitation of a patient's right to privacy or the infringement of a patient's confidentiality. See P Matshidze and L Hanmer 'Health Information Systems in the Private Sector' 2007 *South African Health Review* 99.

²⁷Oosthuizen and Verschoor op cit note 15 at 37-38.

²⁸HPCSA Confidentiality: protecting and providing Information second edition booklet 11 Pretoria, May 2007 para. 2-3.

²⁹Ibid para. 4.

³⁰Matshidze and Hanmer op cit note 26 at 100 and 101.

For the sake of completeness it should be mentioned that South African common law also provides protection and remedies to persons where there is an infringement of their privacy.³¹

(ii) Availability : right of access to information

The disclosure of information is not merely a necessity for people, but an essential and important part of good corporate and state governance in an effective democracy.

To this end, the right of access to information is enshrined in section 32(1) of the Constitution and provides that, '[e]veryone has the right of access to any information held by the state and any information that is held by another person and that is required for the exercise or protection of any rights.'³²

Further, section 32(2) provides that, '[n]ational legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state.'

The resultant enabling legislation, the Promotion of Access to Information Act No.2 of 2000 (PAI Act) fosters a culture of effective and efficient disclosure of information by corporate bodies and government and enables South Africans to more fully exercise and protect their rights to access information.

The PAI Act, which came into operation on 9 March 2001, is of particular importance to the doctrine of informed consent in medical law. The PAI Act establishes voluntary and mandatory mechanisms or procedures to give effect to the right to information, with the purpose of ensuring that a person may gain access to records of a public or private body swiftly, inexpensively and effortlessly, as far as is reasonably possible. Generally the PIA Act seeks to promote transparency, accountability and the effective governance of all private and public bodies.

The right to access records held by private bodies is set out in section 50(1) of the PAI Act and is similar to the right defined for public bodies, with the important

³¹For an infringement of privacy under common law, a plaintiff must show that the following elements are present, namely, there was (a) an invasion of his privacy in the form of disclosure or revelation of his personal information, (b) concerning the plaintiff (c) which is unlawful and (d) intentional (*animus iniuriandi*) and (e) which caused harm or injury to the plaintiff. It is not within the scope of this paper to canvass this however.

³²This right may however be restricted in terms of the general limitations clause set out in terms of section 36, which is that it may be limited by legislation that applies generally to all, where such limitation is 'reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.'

difference³³ that it is only engaged to the extent that the record is required for the exercise or protection of a right.

The right of access to information held by the state is not qualified by the requirement that the information be necessary for the exercise or protection of a right although a qualified right of access to information is established with respect to private bodies and individuals. The so-called 'horizontal' application of the right ensures that the legislation gives full effect to the right to access, not only state-held information, but also a qualified right of access to privately-held information.

In Section 34 of the PAI Act provision is made for the mandatory protection of the privacy of a third party. The section states that the information officer of a public body must refuse a request for access to a record if its disclosure would involve the unreasonable disclosure of personal information about a third party, including a deceased individual, and that a record may only be released with the consent of the individual concerned.

Persons have a right of access to information about the health care services available to them as well as information held by institutions pertaining to them. They also have a right to receive information about any condition or disease from which they may be suffering. This is of particular relevance to e-health initiatives.

(iii) Integrity : right to data protection

Personal information about a patient is recorded in a patient's medical record and may be kept in either paper or electronic form. Although these records may include extensive personal information regarding a patient they usually include medical notes, historical reports, magnetic resonance images and clinical laboratory results. Electronic Patients Records (EPR) convert paper-based documents into a digital or electronic format.³⁴

³³contained in subsection 50(2).

³⁴The health care practitioner acts as an information manager who 'acquires, processes, stores, retrieves, and applies information related to 1) individual patient history and clinical course, 2) diagnostic and therapeutic protocols, 3) disease patterns in patient populations, 4) functioning of the health care system, and 5) the vast store of published knowledge.' The clinical encounter is heavily invested in the obtaining, processing, or applying information. This information is then stored in databases and transferred via the Internet to authorised health-care practitioners who gain access to and use the data. See Adesina et al op cit note 15 at 4 and EE Westberg RA Miller 'The basis for using the Internet to support the information needs of primary care' (1999) 6 *JAMIA* 6.

EPRs are advantageous in that they allow real-time access to medical records and can be easily accessed and updated.³⁵ The corollary to this however is that these benefits need to be balanced against the vulnerability of data to security breaches.

Data security and preserving data integrity is entrenched in section 14 of the Constitution which includes not only the protection against the disclosure of private information to others but also that information held by a third party is done so securely so that an individual's confidentiality, integrity and the availability of data is not compromised.³⁶ The necessary procedures and processes should therefore be developed and implemented so that the integrity and confidentiality of data captured, stored and processed is guaranteed and that an appropriate level of confidence is established and maintained.³⁷ This is in alignment with the World Medical Association recommendation which states that '[b]ecause of the risks of information leakage inherent to some types of electronic communication, the physician has an active obligation to ensure that all established standards of security measures have been followed to protect the patient's confidentiality.'³⁸

Data integrity is not necessarily synonymous with data security. Whereas data security involves safeguarding data against compromise by breaches of disclosure, data integrity as a concept extends to ensuring that the recorded data is accurate and not corrupted.

Legislation has been introduced in South Africa to provide clarity and a means of addresses these issues.

A. Electronic Communications and Transactions Act 25 of 2002 (ECT Act)

Sections 50 and 51 of the ECT Act only applies to personal information that has been obtained through electronic transactions. The ECT Act sets out the accepted data protection principles describing how personal data, as defined in the ECT Act³⁹, may

³⁵Adesina et al op cit note 15 at 3.

³⁶Matshidze and Hanmer op cit note 26 at 100.

³⁷Adesina et al op cit note 15 at 4.

³⁸as cited in C Jack and M Mars 'Telemedicine a need for ethical and legal guidelines in South Africa' (2008) 50(2) *South African Family Practice* 60a at 60c

³⁹Personal information is defined in the ECT Act as 'information about an identifiable individual, including, but not limited to—

(a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the individual;

be collected and used. The ECT Act definition for personal information includes specifically ‘physical or mental health, well-being and disability’.

Section 51 determines that a ‘data controller’⁴⁰ must have the ‘express written permission of the data subject for the collection, processing or disclosure of any personal information on that data subject’. Moreover, sub-section 4 provides that ‘[t]he data controller may not use the personal information for any other purpose than the disclosed purpose without the express written permission of the data subject, unless he or she is permitted or required to do so by law’.⁴¹

A data controller may also not disclose any of the personal information to a third party unless required or permitted by law or specifically authorised by the data subject.⁴²

It is a further requirement that the data controller ‘delete or destroy all personal information which has become obsolete’⁴³ and that ‘[a] party controlling personal information may use that personal information to compile profiles for statistical purposes and may freely trade with such profiles and statistical data, as long as the profiles or statistical data cannot be linked to any specific data subject by a third party’.

Integral to the nature of e-health delivery systems is the sharing and swapping of confidential data which implies the transmission or movement of data from place to

- (b) information relating to the education or the medical, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved;
- (c) any identifying number, symbol, or other particular assigned to the individual;
- (d) the address, fingerprints or blood type of the individual; the personal opinions, views or preferences of the individual, except where they are about another individual or about a proposal for a grant, an award or a prize to be made to another individual;
- (f) correspondence sent by the individual that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;
- (g) the views or opinions of another individual about the individual;
- (h) the views or opinions of another individual about a proposal for a grant, an award or a prize to be made to the individual, but excluding the name of the other individual where it appears with the views or opinions of the other individual; and
- (i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual, but excludes information about an individual who has been dead for more than 20 years’.

⁴⁰A ‘data controller’ means ‘any person who electronically requests, collects, collates, processes or stores personal information from or in respect of a data subject’, as contained in the definitions in s 1 to the ECT Act.

⁴¹s 51(5) of the ECT Act. A record of the personal information disclosed and the specific purpose for which the personal information was collected must be kept for as long as the personal information is used or for at least a year.

⁴²s 51(6) of the ECT Act.

⁴³s 51(8) of the ECT Act.

place. Data security methods, such as cryptography⁴⁴, digital watermarking⁴⁵ and steganography⁴⁶, have been suggested as a means of protecting data.⁴⁷ As the onus is on the data controller to not disclose any information to third parties it may be suggested that it is incumbent upon them to adopt such methods. The ECT Act however is silent on the extent or level of security if any is required – but merely prohibits disclosure to a third party without consent. What therefore would constitute reasonable or adequate security under the circumstances is uncertain. Security methods are canvassed more comprehensively in the introduction by the legislature of POPI.

B. Protection of Personal Information Bill 9B of 2009 (POPI)

The principles set out in the POPI Bill⁴⁸ have a significant impact on data privacy in South Africa specifically for persons who gather, retain, disseminate and dispose of personal information. POPI has as its purpose to promote the protection of personal information processed by private and public bodies thus giving effect to the right of privacy contained in section 14 of the Constitution.

The POPI Bill provides for the safeguarding of personal information as defined.⁴⁹ The Bill seeks to regulate the way personal information is processed and to provide recourse and remedies to those whose rights have been infringed.

⁴⁴Encrypting is a process of obscuring the meaning of the message by digitally 'scrambling' data so that only people who possess the 'key' to the encryption can return the data to its original form.

⁴⁵Digital watermarking involves embedding data (as a watermark) into a multimedia object. The watermark can then be detected or extracted later without impairing the object and is designed to identify the object as authentic.

⁴⁶Steganography involves concealing or hiding information by embedding messages within other, seemingly innocent-looking messages.

⁴⁷Adesina et al op cit note 15 at 5.

⁴⁸approved by the National Assembly on 11 September 2012 and has been referred to the National Council of Provinces for approval

⁴⁹'Personal information' is defined widely as

'information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to—

(a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person;

(b) information relating to the education or the medical, financial, criminal or employment history of the person;

(c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person;

(d) the biometric information of the person;

(e) the personal opinions, views or preferences of the person;

(f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;

(g) the views or opinions of another individual about the person; and

Conditions for the processing of personal information

Any personal information that is processed by a health practitioner either online or not for the purposes of his professional activity will be required to comply with certain conditions imposed by the Bill.

Section 4 of POPI provides for the lawful processing of personal information. Section 4(1) sets out the conditions for the lawful processing of personal information by a responsible party⁵⁰ under the following headings:

- (a) 'accountability',
- (b) 'processing limitation',
- (c) 'purpose specification',
- (d) 'further processing limitation',
- (e) 'information quality',
- (f) 'openness',
- (g) 'security safeguards' and
- (h) 'data subject participation'.

The Bill then comprehensively provides for the conditions under which personal information should be processed.

It is a requirement in section 9 of the Bill that personal information should be processed 'lawfully' and in a 'reasonable manner that does not infringe the privacy' of the person.⁵¹ The Bill further provides that 'personal information may only be processed if, given the purpose for which it is processed, it is adequate, relevant and not excessive'.⁵²

The person from whom data is collected must consent to the processing and be made aware clearly and precisely of the purpose for which the information is to be processed.⁵³ The information must be collected directly from the person and for a

(h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person'

⁵⁰ 'responsible party' means 'a public or private body or any other person which, alone or in conjunction with others, determines the purpose of and means for processing personal information'.

⁵¹ section 9.

⁵² section 10.

⁵³ section 11 and 13.

specified, explicit, and legitimate purpose.⁵⁴ In addition personal information may not be retained for longer than is necessary for the specified purpose and such information should not be used for any other purpose than that for which it was collected.⁵⁵

The responsible party has an obligation in terms of the Bill to take reasonable steps to ensure that information is complete, accurate, not misleading and is updated where necessary.⁵⁶

Further it is incumbent upon the responsible party to put security measures in place to ensure that personal information is safeguarded against loss, damage to and unlawful access to or processing of personal information.⁵⁷

Sections 19 through 21 – security measures

What is of particular relevance to the health care environment is the provisions contained in sections 19 through 21 regarding the security measures on the integrity of personal information. As safeguarding security and the maintenance of data integrity are integral to the provision of privacy it is of utmost importance to emerging e-health processes.

Section 19 of POPI provides that a responsible party 'must secure the integrity and confidentiality of personal information in its possession or under its control' by taking 'appropriate, reasonable technical and organisational measures' to prevent—(a) loss of, damage to or unauthorised destruction of personal information; and (b) unlawful access to or processing of personal information'.

The Bill provides in section 19(2) that the responsible party is obliged to take 'reasonable measures to (a) identify all reasonably foreseeable internal and external risks to personal information in its possession or under its control; (b) establish and maintain appropriate safeguards against the risks identified; (c) regularly verify that the safeguards are effectively implemented; and (d) ensure that the safeguards are continually updated in response to new risks or deficiencies in previously implemented safeguards'.

It is further incumbent upon the responsible party to have 'due regard to generally accepted information security practices and procedures' which may be

⁵⁴section 12 and 13.

⁵⁵section 14 and 15.

⁵⁶section 16(1).

⁵⁷section 19(1).

required in terms of professional rules and regulations in respect of their profession or industry.

Section 20 provides that an operator or any person acting under the authority or on behalf of a responsible party must process information only with the knowledge or authorisation of the responsible party and should 'treat personal information which comes to their knowledge as confidential and must not disclose it unless required by law or in the course of the proper performance of their duties'. This is of particular importance to hospital staff and health care administrators or any person authorised by the health care practitioner to process personal information on their behalf.

Section 21 provides that '[a] responsible party must, in terms of a written contract between the responsible party and the operator, ensure that the operator which processes personal information for the responsible party establishes and maintains the security measures referred to in section 19.' Further, it is the responsibility of the operator 'to notify the responsible party immediately' where personal information has been accessed or acquired by any unauthorised person.

Section 32 – authorisation concerning a person's health or sex life

Section 26 of POPI prohibits the processing of personal information concerning the health, sex life or biometric information of a person.

However the prohibition contained in section 26 does not apply to the processing of information by certain categories of persons and institutions including, but not limited to, 'medical professionals, healthcare institutions or facilities or social services, if such processing is necessary for the proper treatment and care of the data subject, or for the administration of the institution or professional practice concerned'.

The prohibition does not apply where it is necessary to supplement the processing of personal information concerning a person's health with a view to the proper treatment or care of the person. Information regarding the health, sex life as well as biometric information may only be processed by responsible parties 'subject to an obligation of confidentiality by virtue of their office, employment, profession or legal provision' or if 'established by a written agreement' between the responsible party and person.

Section 32(5) provides that '[p]ersonal information concerning inherited characteristics may not be processed in respect of a data subject from whom the

information concerned has been obtained, unless—a serious medical interest prevails; or the processing is necessary for historical, statistical or research activity.'

Of what significance is POPI to e-health?

Some means of pre-emptive caution is undoubtedly required in allowing unrestricted access to personal data. However, to facilitate optimal care e-health practitioners would require freer access parameters within which to work. The access and transferability of patient's medical records, such as the history of their condition, previous diagnoses and treatments are relevant in providing quality treatment.⁵⁸ The prohibition on processing health information does not apply to certain categories of persons, including medical professionals, where such processing is necessary for the proper treatment or care of the person. Failing this, authorisation to process the personal information regarding health can always be provided through written consent.

POPI certainly defines attributes for role-based access and the developing of policies to protect the patient's right to privacy with regard to their medical data. The requirement for 'written' consent may prove to be problematic and burdensome in an electronic environment. Although one could ostensibly rely on the provisions of the ECT Act to negate this hardship, ideally provision should be made for digitally obtained consent and electronic signature in POPI.

Informed consent is intrinsically linked to confidentiality⁵⁹ and the threat of data compromise is address by POPI and is to be welcomed.

The Bill provides that 'appropriate, reasonable technical and organisational measures' to prevent 'loss of, damage to or unauthorised destruction' or 'unlawful access' to personal information' should be taken. It is however not entirely clear what these 'appropriate and reasonable measures' would be and what would be considered sufficient security in an e-health environment. Whether it would be considered reasonable and appropriate security, for instance, to use e-mail encryption software available in commercial packages such as Microsoft Outlook®, which requires little more than the 'unlocking' of an email message by the recipient by means of an

⁵⁸Adesina et al op cit note 15 at 2.

⁵⁹C Jack and M Mars 'Telemedicine a need for ethical and legal guidelines in South Africa' (2008) 50(2) *South African Family Practice* 60a at 60c.

encryption key, remains to be seen.⁶⁰ Likewise, the level of security that will be considered sufficient on the hard drives of personal computers of health care practitioners where patients' health records are stored, or who participate in 'store and forward' e-mail based telemedicine as well as those who participate in online e-health discussion or advice forums, will have to be determined.⁶¹ It may well be left to the judiciary to establish the precise meaning and extent of these concepts, although greater clarity in this respect will most certainly be needed going forward.

(c) Licensing, accreditation and registration of health care practitioners

For e-health to be successful the ability to practice health care at a distance must become a reality. Licensure is perhaps one of the 'single largest hurdles to address' in e-health and would require the most global cooperation, standardisation and co-ordination.⁶²

The requirement for registration by authorities in a particular jurisdiction is necessary for the adherence and maintenance of medical quality and safety standards by the practicing health practitioners thus protecting its people from harm or injury.⁶³

Each jurisdiction usually has its own strict regulation of the registration, accreditation and licensing of the members of its health practitioners.⁶⁴ Although requirements differ the general position in the United States is that a health practitioner cannot practice medicine in a particular jurisdiction if not registered in that jurisdiction.⁶⁵

In the United States, health practitioners receive a licence to practice medicine and are bound by the laws of the individual states in which they are licensed.⁶⁶ Legislation differs from state to state with certain states allowing the practice of medicine across state boundaries.⁶⁷ Where health practitioners wish to provide health

⁶⁰Ibid and Kekana et al op cit note 18 at 33.

⁶¹Ibid.

⁶²L Rannefeld 'The doctor will e-mail you now: Physicians' use of telemedicine to treat patients over the Internet' (2004) 19 (1) *Journal of Law and Health* 75 at 103.

⁶³A Le Roux 'Telemedicine: A South African legal perspective' (2008) (1) *TSAR* 99 at 105.

⁶⁴Ibid.

⁶⁵Rannefeld op cit note 62 at 92.

⁶⁶M Tremblay 'Telemedicine: Legal Issues A policy overview paper' 1997 *Rainmaker Publications* 8.

⁶⁷Of the state boards in the United States, 57 require that doctors practicing telemedicine be licensed in the state in which the patient is located. Ten state boards require a 'special purpose licence, telemedicine licence or certificate, or licence to practice medicine across state lines to allow for the practice of

services in a particular jurisdiction, they will be required to meet all the requirements for registration in that particular jurisdiction and register themselves with that authority.⁶⁸ Unfortunately this process can be time-consuming and place an administrative burden on the authorities – one which is best avoided by health practitioners where possible.⁶⁹

A further uncertainty exists in determining under which authority the e-health practitioner should be registered where the patient receives treatment or advice across-jurisdictions, for instance, over the Internet or Skype. Should the practitioner be registered in the place where the patient resides, where they receive the treatment or at the practitioner's usual place of business.⁷⁰

A possible solution to the issue of registration is in the mutual recognition between states of licences across borders or alternatively limiting licensing to allowing health care practitioners to only treat specific conditions and/or to restrict the performance of certain functions.⁷¹

The position in South Africa is strictly regulated by the HPCSA and requires that a health practitioner only practice his profession if registered and licensed for the particular occupation with the HPCSA.⁷² However, existing systems of licensing and regulation of health practitioners may be inadequate to accommodate practitioners whose role is clearly intermediary or advisory, and who may not actually 'practice' any clinical profession.⁷³

Foreign health practitioners who wish to practice medicine from outside the borders of South Africa, that is via various e-health initiatives, are required to meet the criteria as set out, and register, with the particular professional board of the HPCSA.⁷⁴

In the EU the E-Commerce directive is applicable and the normal medical licence is sufficient as the European member states recognise their neighbouring states medical qualifications. The approach of mutual recognition has been adopted by the European Union in an attempt to facilitate cross border practice. In this regard no special licence for providing E-health services between member states is imposed.

telemedicine?..See Federation of State Medical Boards 'Telemedicine Overview' 2012 Available at <http://www.fsmb.org/pdf/grpol_telemedicine_licensure.pdf> Accessed 1 February 2013.

⁶⁸Rannefeld op cit note 62 at 94.

⁶⁹Le Roux op cit note 63 at 105.

⁷⁰Ibid at 106.

⁷¹Ibid.

⁷²Ibid.

⁷³Tremblay op cit note 66 at 8.

⁷⁴Le Roux op cit note 63 at 106.

It is debatable whether there should be a specific need for health professionals to be specially licensed and accredited to use e-health applications. Although newer technologies and apparatus may require instruction and education to operate, it is suggested that if the use of the telephone has not previously required regulation or guidelines, why then should the need for newer forms of e-health require specific registration or regulation.

Guidelines on the use of e-health in different clinical specialties emphasise that an e-health consultation or encounter should be no different to routine practice and there should therefore be no additional risk to the patient. It is suggested that specialist disciplines should, through their professional organisations and associations, draft appropriate clinical, technical and operational guidelines and if necessary, ethical guidelines, relevant to e-health with regard to the South African context. Currently the position in South Africa seems to be that any health professional may practice e-health in South Africa, as long as they are registered health practitioners with the particular professional board of the HPCSA. The requirement to be specifically registered as an e-health practitioner is inappropriate and seems unnecessary in a country with a chronic shortage of health practitioners especially in rural areas.

(d) Doctor-patient relationship

(i) Doctor-patient : duty of care

The relationship between doctor and patient is unique and is a prerequisite for the establishment of a duty of care.⁷⁵ Although an e-health interaction would not ostensibly change this fundamental principle it may be unclear at which point a duty of care has been established and with whom the relationship exists.

Certainly, clinical practice standards should apply regardless of whether technology is introduced into the health care process or not.⁷⁶ The interaction between health care practitioner and patient, while using a technological platform as a means of health care delivery, should not diminish the obligation on the health care practitioner to meet certain clinical standards or the right to autonomous decision making of the

⁷⁵Rannefeld op cit note 62 at 80.

⁷⁶Tremblay op cit note 66 at 8.

patient.⁷⁷ Similarly, any shortcomings inherent in the use of technological platforms should not play a mitigating factor in the failure to achieve these standards.⁷⁸

The conventional, traditional approach to the patient-doctor relationship does not necessarily sit comfortably with the advancement of e-health. Bosslet found that the social media ‘can dramatically blur the line between public and private spaces’. The permanent nature of postings online means ‘that the control over information dissemination, once posted, differs significantly from a fleeting and local interaction within the hospital or outpatient office’.⁷⁹ This raises questions concerning the nature of patient–doctor boundaries in the digital age.

Concepts such as standard of care may require re-evaluation in the context of e-health. The applicable standard of care is that ‘ordinarily exercised by the average medical practitioner under the same or similar conditions in comparable circumstances’.⁸⁰ This is determined with reference to the type of resources available and circumstances within which the practitioner finds himself and whether it can be said that the health practitioner performed his duties with the level of skill and diligence required of and exercised by other similar health practitioners under comparable conditions.⁸¹

It is incumbent on the patient to prove that a doctor-patient relationship was established, that the health practitioner had a duty to act with the necessary standard of care and that the breach of this standard of care caused the patient damage or harm.

The difficulty with the standard of care concept in finding application in an e-health context is that jurisdictions differ in their understanding of standard of care with certain jurisdictions applying a lower standard of care than others.

Although it is unclear what the standard of care imposed on health practitioners providing e-health services should be, it is posited that the standard of care in a particular jurisdiction should be the same as it is for other similar health care

⁷⁷Edison et al op cit note 5 at 797.

⁷⁸Tremblay op cit note 66 at 9.

⁷⁹GT Bosslet 'Commentary: The Good, the Bad, and the Ugly of Social Media' (2011) 18 *Academic Emergency Medicine* 1221 at 1222 and GT Bosslet AM Torke SE Hickman CL Terry PR Helft 'The patient-doctor relationship and online social networks: results of a national survey' (2011) 26 *J Gen Intern Med* 1168 at 1172.

⁸⁰Le Roux op cit note 63 at 111.

⁸¹Le Roux op cit note 63 at 109.

procedures in that jurisdiction.⁸² It is not inconceivable that the standard of care actually increases in e-health applications as access to the latest information becomes easier with the use of technology and health care practitioners have an opportunity to more easily remain informed about their patients' well-being as well as current developments in their field.

The legal and ethical requirements for health care practitioners to conduct assessments and investigations according to established standards of care are not obviated by using the social media as an alternative health care platform.

It is envisaged by Poe that 'as technology advances and e-health services become generally more available the use of telemedicine services may also become the necessary standard practice expected of physicians'.⁸³ However because of the restrictive conditions under which the HPCSA guidelines propose that telemedicine be practiced in South Africa regrettably there is limited opportunity for this expectation to materialise.

(ii) Doctor-patient relationship : a more participative arrangement?

In the 1950s sociologist Talcott Parsons on describing the concept of the 'sick role' found that the doctor's role in the health care encounter to be one based largely on a high degree of specialisation, professionalism and the application of expert medical knowledge and technical competence.⁸⁴ Doctors maintained a 'dominant autonomous authority', while patients occupied a 'more passive, submissive role'. This entrenched power imbalance continued well into the late 1970s.⁸⁵

In the 1980s a fundamental shift away from the passive acceptance of doctor's advice and unquestioning admiration and acceptance of medical practitioners authority together with a degree of disillusionment with the traditional health care structures occurred.

⁸²D Svantesson 'Legal liability for Internet based cross-border provision of medical advice, information and products' 2003 *9th Greek-Australian Legal and Medicine Conference* Rhodes Greece <<http://www.lmconference.com.au/papers/2003/svantesson.html>> Accessed 10 January 2013

⁸³K Poe 'Telemedicine liability: Texas and other states delve into the uncertainties of health care delivery via advanced communications technology' (2001) *The Review of Litigation* 693.

⁸⁴MZ Varul 'Talcott Parsons, the Sick Role and Chronic Illness' 2010 16 *Body & Society* 72-94 Available at <<http://bod.sagepub.com.ezproxy.uct.ac.za/content/16/2/72.full.pdf+html>> accessed 12 February 2013.

⁸⁵SE Burke 'The doctor-patient relationship: An exploration of trainee doctors' views' PhD Thesis, University of Birmingham 2008 45. Available at <<http://etheses.bham.ac.uk/125/>> accessed 19 February 2013.

With wider and more vocal consumer protection in the 1980s the sick abandoned the role of ‘child’ accepting medicine from a paternalistic doctor and began to assume the role of ‘adults’ capable of independent and informed decision-making. This new found trend of people taking greater responsibility for their health, increased information seeking and involvement in decision-making, the need for self-determination and autonomy, coupled with a willingness to challenge the power that doctors’ exercise over them, has changed the doctor-patient relationship in contemporary, western society.⁸⁶

Interactions between doctors and patients do not exist in a vacuum and are influenced by the socio-cultural context within which they occur.⁸⁷ Although patients have become more consumerist and the balance has shifted towards greater patient autonomy, it is argued by Bury ‘that the medical profession remains firmly in control of key decisions concerning treatment and that patients continue to expect this to be the case’.⁸⁸ What does seem to be clear though is that health care interactions are unlikely to be that of the so-called ‘medical dominance’ of health care professions over patients of the past described by Bury.⁸⁹ Interactions are anticipated to be far more complex in the future with relationships based primarily on that of ‘health partnerships’ with an ‘active or expert patient’ being seen as the way forward.⁹⁰ As Coulter has suggested paternalism, although still by and large widespread, and as well intentioned as it may be, creates an unhealthy dependency on health professionals that is ‘out of step’ with other trends in society. Patients are ‘growing up’ and professionals are required to accommodate it.⁹¹

With this in mind it is suggested that the concept of a doctor-patient relationship as one of a partnership should be examined more closely and further developed. A future relationship based on partnership would thus be one of more empowerment of patients, sharing of the decision making processes and promoting self-management of their conditions.

⁸⁶Ibid and A Le Roux-Kemp ‘A legal perspective on the power imbalances in the doctor-patient relationship’ unpublished thesis 2010 Stellenbosch University 251.

⁸⁷Ibid.

⁸⁸M Bury ‘Researching patient-professional interactions’ (2004) 9 suppl. *Journal of Health Services Research and Policy* 48 at 52.

⁸⁹Ibid at 48.

⁹⁰Ibid at 52.

⁹¹A Coulter ‘Paternalism or partnership? Patients have grown up and there’s no going back’ (1999) 319 *BMJ* 719–720.

In South Africa a doctor-patient relationship is formed when both the patient and doctor have come to a mutual agreement, usually an implicit agreement at the time of consultation, that the doctor will 'accept and treat the person as the patient' and the patient will submit to such care.⁹² Personal or physical contact between doctor and patient is not necessarily a prerequisite in the formation of the relationship. Instead, of significance is the fact 'that a particular medical practitioner performs medical services to the benefit of a patient'.⁹³

At present there is no South African case law regarding e-health specifically. With websites offering 'ask-the-doctor' services, where patients can ask questions to health professionals via email or other means of telecommunication, it is not entirely clear whether these interactions constitute medical practice, and whether doctors have the ethical obligation to respond to unsolicited patient emails.⁹⁴

In the American case of *Bienz v. Central Suffolk Hospital*⁹⁵ the court indicated that a conversation over the telephone in which a doctor provided advice to the patient, and upon which the patient relied, was sufficient to establish a doctor-patient relationship and consequently gave rise to a duty of care on the part of the doctor. Where the doctor provides some level of evaluation of the patient's condition, and the patient relies upon the advice given by the doctor, a relationship is formed and a duty is established.

Whether a doctor-patient relationship is formed is therefore a question of fact which will depend on the particular circumstances of each case. It is necessary to clearly determine whether a doctor-patient relationship is established during an e-health interaction and if so who the parties to such a relationship are.

In the case of *Lopez v Aziz*⁹⁶ the court found that a doctor-patient relationship was not established when a consulting obstetrician talked to the patient's regular physician by telephone. As the defendant did not contact, examine, or treat the plaintiff, nor was the plaintiff referred to the defendant for any treatment or consultation, and the defendant's opinions regarding the course of treatment were

⁹²A Le Roux-Kemp 'A legal perspective on the power imbalances in the doctor-patient relationship' unpublished thesis 2010 Stellenbosch University 1 at 13.

⁹³Ibid.

⁹⁴G Eysenbach 'Towards ethical guidelines for dealing with unsolicited patient emails and giving teledvice in the absence of a pre-existing patient-physician relationship systematic review and expert survey' (2000) 2(1) *J Med Internet Res* e1 at e1 Available at <<http://www.jmir.org/2000/1/e1/>>

⁹⁵*Bienz v. Central Suffolk Hospital*, 557 N.Y.S. 2d 139. 1990

⁹⁶*Lopez v. Aziz*, 852 S.W.2d 303, 306 Tex.App. B San Antonio 1993.

addressed to the plaintiff's physician directly, who was free to accept or reject those opinions as he saw fit, no doctor-patient relationship existed.

The court went on to hold that 'the extension of potential malpractice liability to doctors with whom a treating physician has merely conferred, without more, would unacceptably inhibit the exchange of information and expertise among physicians. This would benefit neither those seeking medical attention nor the medical profession'.

However, a doctor-patient relationship was found to exist in *Wheeler v. Yettie Kersting Memorial Hospital*⁹⁷ where an on-call doctor used information obtained by telephone regarding the status of a woman in labour to refer the woman to a hospital. In light of the fact that the doctor assessed the patient's condition and recommended treatment over the telephone, the court held that a doctor-patient relationship did in fact exist.

The finding in *Wheeler* confirms the position that even though a patient may not be in the same room as a doctor, a doctor-patient relationship may still be formed. It further suggests that a doctor-patient relationship can arise by the use of telemedicine or e-health consultations to diagnose or treat a patient.

Potential problems may arise, however, in determining joint and several liability for doctors involved in an telemedicine consultation. In telemedicine consultations more than one doctor is involved, the referring doctor, usually at the same location as the patient, and the doctor consulting via telemedicine. The patient is still ostensibly under the care of the referring doctor and who does not have to follow the advice provided by the doctor party to the telemedicine consultation. This differs from traditional referrals, where a doctor refers the patient to a specialist, who then takes over the responsibility for diagnosis and continued treatment of the patient.

In the case of *Dougherty v Gifford*⁹⁸ the Court of Appeals of Texas found that a doctor-patient relationship was established between a pathologist and a patient even where no physical contact between the doctor and the particular patient was present. The court found that the absence of physical contact between a patient and a practitioner in no way precluded the formation of a doctor-patient relationship. This is of particular interest as e-health interactions frequently occur devoid of direct physical

⁹⁷*Wheeler v. Yettie Kersting Memorial Hospital* 866 S.W.2d 32, 37-40 (Tex.App.-Houston [1st Dist] 1993).

⁹⁸*Dougherty v Gifford* 826 SW 2d 668 Tex: Court of Appeals, 6th Dist. (1992)

contact between the health care practitioner and the patient.⁹⁹ Based on this it would appear that even minimal contact between doctors and patients for instance via telemedicine or online e-health interactions, may be sufficient to establish a doctor-patient relationship.¹⁰⁰

Case law in the United States seems to suggest further that a doctor's participation in a telemedicine consultation, irrespective of whether or not the advice is followed, establishes a doctor-patient relationship. Although South African courts are not bound by foreign case law, section 233 of the Constitution gives a clear instruction to interpret legislation in a manner that is consistent with international law, which would include foreign case law.

The HPCSA proposed guidelines advise that telemedicine only be conducted where face-to-face consultation between the patient and the practitioner is not possible, that is, where there has been a prior relationship and previous face-to-face consultation with the health care practitioner.¹⁰¹ The HPCSA further states that 'all first-time tele-consultations are restricted to situations where a primary health care practitioner is involved in a face-to-face consultation and physical examination of the patient is performed'.

This has implications to e-health initiatives as face-to-face and physical proximity is not always possible. The guidelines are silent, although strongly suggest that online health care consultations via technologies such as Skype or the use of digital photographs would not be acceptable. The position regarding the use of a 'pharmacy extender' or a health care practitioner such as a clinic nurse, who physically examines the patient and acts as the 'eyes and ears' of the doctor as canvassed in the SA 'Hello Doctor' model is also not clear but would ostensibly also not be acceptable according to the guidelines as currently proposed.

Clearly, the relationship between doctor-patient is a complex one and the ordinary principles of contractual and delictual liability cannot always be simply or easily applied. I would suggest that the nature and extent of the interaction experienced in the e-health encounter would determine whether a doctor-patient relationship is established. Whereas merely providing health care information may not

⁹⁹Rannefeld op cit note 62 at 81.

¹⁰⁰R Sivaswamy J Kumar, J 'Doctors on the Internet - Legal and Practical Implications' (2002) 12 *Eubios Journal of Asian and International Bioethics* 185-188.

¹⁰¹HPSCA 'Draft document of the Human Rights, Ethics and Professional Practice Committee of the Health Professions Council of South Africa' 2008 Available as minutes from HPCSA secretary available at <<http://www.hpcsa.co.za/>>

establish such a relationship, the providing of advice, diagnoses or treatment almost certainly would. The redefining and expansion of the patient-doctor relationship is called for and requires further development to bring about a more equal distribution of power.¹⁰²

(e) Establishment of an electronic contract

In South Africa the relationship between a health care practitioner and a patient is based on contractual agreement. A contract is ‘an agreement which is or is intended to be enforceable at law’.¹⁰³ With regard to e-health this contractual relationship may be conducted partially or wholly electronically in an online environment. Persons can conclude legally valid and binding agreements electronically when interacting online.¹⁰⁴

The law governing electronic contracts, the so-called ‘lex informatica’ or cyber law, is a new source of law comprising principles of South African common law, statutory legislation, international model law and conventions, constitutional principles and a body of emerging South African case law.¹⁰⁵ As jurisprudence has not yet been extensively developed in South Africa reliance is placed on international law to provide guidance in the interpretation of South African law.

The United Nations Commission on International Trade Law (UNCITRAL) adopted the UNICITRAL Model Law on E-Commerce¹⁰⁶ in June 1996 with the aim of providing countries with internationally acceptable rules that can be used by national legislators in the drafting of laws enabling and facilitating commercial transactions using electronic means. The UNICITRAL Model Law on E-Commerce adopts the principles of non-discrimination, technological neutrality and functional equivalence. The principle of non-discrimination provides that any document would not be denied legal effect, validity or enforceability solely on the grounds that it is in electronic form. The principle of technological neutrality enforces provisions that are neutral

¹⁰²C Bateman ‘Cutting-edge telemedicine venture freezes as official bodies frown’ (2011) 10 (6) *SAMJ* 368 at 372 and Le Roux-Kemp op cit note 92 at 189.

¹⁰³RH Christie *The Law of Contract* (4th Ed), 2001 Pretoria: Lexis Nexis 2.

¹⁰⁴DJ Loetz C du Plessis ‘Electroniese Koopkontrkte: ‘n tegnologiese hemel of hel (deel-1)’ (2004) 1 *De Jure* 1.

¹⁰⁵S Snail ‘Electronic Contracts in South Africa – *A Comparative Analysis*’ (2008) 2 *Journal of Information, Law & Technology (JILT)* 1 at 5 Available at <http://go.warwick.ac.uk/jilt/2008_2/snail> Accessed 10 January 2013.

¹⁰⁶Available at <http://www.uncitral.org/uncitral/uncitral_texts/electronic_commerce/1996Model.html>

with regard to the technology used and functional equivalence establishes criteria under which electronic documents may be considered equivalent to paper-based documents.

Although the UNCITRAL Model Law on E-Commerce is not legally binding on South Africa, it was largely influential in the drafting of the provisions of the ECT Act.

In South Africa electronic transactions and data communications are governed by the ECT Act which seeks to promote legal certainty regarding electronic contracts. Sections 12 and 13 of the ECT Act provide that electronically negotiated and signed contracts are both legally valid and enforceable. The contractual requirement to reduce an agreement to writing and by signature of the parties thereto will be satisfied if the parties do so by way of an 'electronic data message' as defined in the Act in terms of Section 11(1) of the ECT Act. Moreover, provisions regarding the time and place where the contract is concluded are likewise set out in Section 22(2) of the ECT Act.

The formation of a contract was considered in the case of *Jafta v Ezemvelo KZN Wildlife*¹⁰⁷ where it was held that an e-mail and/or SMS communication was a valid means of concluding a contract of employment.¹⁰⁸ Likewise the Labour Court in *Mafika v SABC*¹⁰⁹ found that where a communication, in this instance, a resignation is sent by SMS it is considered a communication in writing. The court quoted section 12 of the ECT Act which provides: '[a] requirement in law that a document or information must be in writing is met if the document or information is- (a) in the form of a data message; and (b) accessible in a manner usable for subsequent reference.'

Section 1 of the ECT Act defines a 'data message' to mean 'data generated, sent, received or stored by electronic means...'. The applicant's resignation by SMS was therefore found to be a resignation submitted in writing.

Emails and SMS s, although often drafted in casual language, may sufficiently signify the intent to be contractually bound. This is further entrenched in sections 11(1) and 22 of the ECT Act that provides that a digitally negotiated and/or electronically concluded contract is valid and enforceable. The rules governing the

¹⁰⁷2008 10 BLLR 954 (LC); 2008 JOL 22096 (LC).

¹⁰⁸D Collier 'Email and SMS contracts' (2008) 16 (1) *Juta's Business Law* 20.

¹⁰⁹*Mafika v SABC Ltd* 2010 5 BLLR 542 (LC).

time and place of conclusion of the contract are governed under section 22 (2) of the ECT Act.¹¹⁰

In line with the concept of ‘party autonomy’ and the use of data messages as defined in the ECT Act the conclusion of a contract is at the discretion of the contracting parties. This is further contained in the Model Law which specifically permits parties to decide on the formalities of their e-contracts by choice or tacit consent.

Despite the recognition of various forms of expressing intention to be contractually bound by electronic means, it remains unclear whether clicking on an icon on a website would constitute a legally recognisable act sufficiently signifying a party’s intention to be contractually bound where terms are unilaterally imposed.

It may be argued that clicking 'I agree' amounts to 'signing' or at least assenting to the terms and conditions.¹¹¹ Although 'click-wrap' agreements have yet to be tested by the courts in South Africa, Pistorius is of the opinion that, 'there would appear to be no reason as to why they should not be enforceable ... with click-wrap agreement the customer is aware of the contractual terms before a commitment is made to acquire the good or services'.¹¹²

It would appear that nothing precludes parties from e-contracting by means of so-called 'click-wrap' or 'web-wrap' agreements where the online party 'clicks' on certain icons indicating acceptance to the terms and 'agrees' to be bound.¹¹³ Although nothing in common law exists confirming the validity and enforceability of such agreements, section 22 (1) of the ECT Act provides that, '... an agreement is not without legal force and effect merely because it was concluded partly or in whole by means of data messages'.

¹¹⁰ Further section 23 (a) & (b) of the ECT Act provides

‘A data message –

(a) used in the conclusion or performance of an agreement must be regarded as having been sent by the originator when it enters an information system outside the control of the originator or, if the originator and addressee are in the same information system, when it is capable of being retrieved by the addressee (b) must be regarded as having been received by the addressee when the complete data message enters an information system designated or used for that purpose by the addressee and is capable of being retrieved and processed by the addressee;’ and

Section 23 (c) of the ECT Act states

‘(c) must be regarded as having been sent from the originator’s usual place of business or residence and as having been received at the addressee’s usual place of business or residence.’

¹¹¹ Snail op cit note 105.

¹¹² T Pistorius ‘Formation of Internet contracts: Contractual and security issues’ (1999) 11 *SA Mercantile Law Journal* 282 at 292.

¹¹³ T Pistorius ‘Click-wrap and web-wrap Agreements’ (2004) 16 *SA Mercantile Law Journal* 568 at 569-570.

Section 24 of the Act provides for the valid expression of intent to make an offer or acceptance by means of a data message and 'is not without legal force merely because it is in data form without an electronic signature'. This section strengthens the legal effectiveness of data messages used in electronic communications and would by all accounts extend to the establishment of a contractual agreement of service between doctor/health practitioner and patient.

(f) Informed consent

The doctrine of informed consent is entrenched in South African common law, case law and legislation, in which effect is given to the protection of an individual's right to physical integrity and self-determination provided in the Constitution.

In South African medical law, patient autonomy is upheld with the ultimate decision to proceed or refuse any form of medical treatment, be it therapeutic, non-therapeutic or diagnostic, resting with the patient and not with the medical practitioner.¹¹⁴ The doctrine supports freedom of choice and applies even if a refusal on the part of the patient to undergo the treatment would be grossly unreasonable and may result in injury or death.¹¹⁵

The doctrine of informed consent in South African medical law was upheld in the decision of *Castell v De Greef*.¹¹⁶ Scott J while acknowledging the requisite duty of care, diligence and skill, recognised and appreciated that mishaps can and do occur. The defendant, a plastic surgeon, who after performing a bilateral mastectomy and prosthetic breast reconstruction that subsequently became infected resulting in necrosis, was found not to be negligent. The court found that since infection is an inherent risk in any surgical procedure, the fact that it occurred (*res ipsa loquitur*) did not confer negligence on the part of the doctor.

The significance and effect of the decision by the court in *Castell v De Greef* was that it accepted and incorporated the doctrine of informed consent in South

¹¹⁴P Carstens 'Informed Consent in South African Medical Law with reference to legislative developments' *The South African Medico Legal Society* Available at <<http://new.samlis.co.za/node/410>> Accessed 26 December 2012 and H Oosthuizen T Verschoor, T 'Ethical principles becoming statutory requirements' (2008) 50 (5) *SA Family Practice* 36 at 38.

¹¹⁵TL Beauchamp and JF Childress *Principles of Biomedical Ethics* 1994 Oxford University Press at 120 and KE Edison DA Fleming and H Pak 'Telehealth ethics' (2009) 15 (8) *Telemedicine and e-health* 797 at 797.

¹¹⁶*Castell v De Greef* 1994 (4) SA 408 (C).

African law, rejected medical paternalism in favour of patient autonomy, established the lack of informed consent as an issue of assault and not negligence; and lastly but importantly, established the determination of the 'reasonable patient' as the test for informed consent thus rejecting the position found in English case law of the 'reasonable doctor'.¹¹⁷ It was held by the court that 'a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.'

Chapter 2 of the Constitution promotes, inter alia, the values of bodily integrity, self-determination and human dignity of all the people in South Africa. Section 12(2) protects the freedom and security of the person including the 'right to bodily and psychological integrity, which includes the right -

- (a) to make decisions concerning reproduction;
- (b) to security in and control over their body; and
- (c) not to be subjected to medical or scientific experiments without their informed consent.'

To give effect to the right contained in the Constitution, the National Health Act entrenches the doctrine of informed consent in terms of its definition, scope and requirements. In terms of section 6, the user must be informed of their health status, the diagnostic procedures and treatment options available, the benefits, risks and costs of the options available to them and the right to refuse such treatment.¹¹⁸

Further section 6 (2) creates an obligation on the health care provider to where possible inform the user 'in a language that the user understands and in a manner which takes into account the user's level of literacy'.

¹¹⁷Carstens op cit note 102. It should be borne in mind that the legal consequences of medical treatment without informed consent is that the doctor may incur liability for (a) breach of contract; (b) civil or criminal assault (a violation of bodily integrity); (c) civil or criminal iniuria (a violation of dignity/privacy) or (d) negligence.

¹¹⁸In terms of section 6 of the Act '[e]very health care provider must inform a user of-

- (a) the user's health status except in circumstances where there is evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
- (b) the range of diagnostic procedures and treatment options generally available to the user;
- (c) the benefits, risks, costs and consequences generally associated with each option; and
- (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.'

Section 7 of the Act provides for certain exemptions to the general rule contained in section 6, and provides that health service may not be provided to a user without the user's informed consent, unless certain circumstances exist.¹¹⁹

Once the requisite information has been obtained, a patient must still be advised that they are entitled to participate in the decisions made about their treatment. For the purposes of section 8 of the Act this is achieved by obtaining the patient's informed consent even if consent was obtained initially from another person, as referred to in terms of section 7, or if the patient is a minor or 'lacks the legal capacity to give the informed consent'. In the event that the patient was unable to furnish their consent before the procedure was performed or treatment provided, the patient's informed consent should be obtained after the procedure or treatment.

The HPCSA Telemedicine Guidelines propose detailed and extensive procedures that should be followed when conducting a telemedicine consultation.¹²⁰ For every telemedicine encounter, written, informed consent should be given by the patient to the health care practitioner for every aspect of that telemedicine encounter, after a full disclosure in made of all the material facts.¹²¹ The guidelines stipulate that a consent form be provided 'in writing' with a copy of the form kept with the patient's records¹²² and a duplicate given to the patient. This would include the transfer of patient records, storage of information, clinical examinations and consultation with another practitioner electronically. In addition, consent by the patient to the use of

¹¹⁹ '(a) the user is unable to give informed consent and such consent is given by a person-
 (i) mandated by the user in writing to grant consent on his or her behalf; or
 (ii) authorised to give such consent in terms of any law or court order;
 (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;
 (c) the provision of a health service without informed consent is authorized in terms of law;
 (d) failure to treat the user, or group of people which includes the user will result in a serious risk to public health; or
 (e) any delay in the provision of the health service to the user might result in his her death or irreversible damage to his or her health'.

¹²⁰ 2008 Draft document of the Human Rights, Ethics and Professional Practice Committee of the Health Professions Council of South Africa. Available as minutes from the HPCSA secretary at <<http://www.hpcsa.co.za>>

¹²¹ Kekana et al op cit note 18 at 35.

¹²² A patient record is 'any relevant record made by a health-care practitioner at the time of or subsequent to a consultation and or examination or the application of health management' See A De Klerk 'The right of patients to have access to their medical records: The position in South African law' (1993) 12 *Med Law* 77–83 as cited in Adesina et al op cit note 15 at 3.

electronic medical technology during the e-health consultation and to the sharing of their information with other health care practitioners will be required.¹²³

Whether it should be necessary at all to obtain written informed consent by health care professionals in developing countries is debatable.¹²⁴ It is suggested in Jack that the imposition of signed informed consent by regulators in a country such as South Africa with low literacy levels would be unduly onerous and would serve to impede telemedicine and e-health usage rather than enable it. A move to an implied consent model may be of benefit especially in the practice of synchronous telemedicine although a so-called 'one size fits all' approach may not be entirely appropriate.¹²⁵

Despite the formality for consent to be 'in writing', section 12(a) and (b) of the ECT Act may provide some relief to e-health practitioners by recognising data messages¹²⁶ as the functional equivalence of writing and as having the same legal value as a message written on paper. Section 24 of the ECT Act provides for the valid expression of intent by means of a data message and provides that it 'is not without legal force merely because it is in data form without an electronic signature'.

This may be useful in e-health encounters as the legal recognition of informed consent given electronically in the form of a data message may be sufficient to give it legal force and effect.

¹²³M Mars and C Jack 'Why is telemedicine a challenge to the regulators? (2010) 3 (2) *SAJBL* 55 at 57

¹²⁴M Mars and C Jack 'Informed Consent for Telemedicine in South Africa: Clinical Practice versus the Legislators' in *South African Telemedicine Conference* Cape Town 2010.

¹²⁵Mars and Jack op cit note 123 at 57.

¹²⁶defined above.

IV. CHAPTER 4 : E-HEALTH APPLICATIONS

(a) International Examples

(i) United States - 'Hello Health'¹

'Hello Health' is a United States based primary health care practice that is described as 'fast becoming an emblem of modern medicine'.² It is a paperless, web-based social media platform that essentially provides primary health care services to patients and a practice management system for doctors.

Depending upon the nature of the patient's symptoms, the patient may instant message, make an appointment for a house/office call, video chat, or send an email to one of the doctors online through 'Hello Health's' web site. 'Hello Health' provides a confidential and secure social network platform through which its doctors' advise, treat and stay in touch with their patients. Patients can schedule appointments online, communicate with their doctor in real-time, email follow-up questions to their doctors, manage their laboratory results and request prescription renewals.

Although 'Hello Health' only opened in 2008, many patients and doctors alike in the United States believe 'this type of practice is the way to practice medicine'.³ 'Hello Health' has in addition developed a social networking feature to the technology platform, so that doctors can 'friend' each other, obtain referrals and/or communicate and advise each other. 'Hello Health' describes its platform as a method of using today's tools, to 'enable the community of patients and doctors to communicate better.'

(ii) European – 'Dokter.nl'⁴

As a response to the need for personal, reliable, easy and quick doctor consultations Dokter.nl Digital Consultation was developed in the Netherlands. The medical process

¹ Hellohealth.com <<http://www.hellohealth.com>>

² C Hawn 'Take Two Aspirin And Tweet Me In The Morning: How Twitter, Facebook, And Other social Media Are Reshaping Health care' (2009) 28 (2) *Health Affairs* 361 at 362.

³ Ibid.

⁴ dokter.nl <<http://www.dokter.nl>>

from triage, patient/doctor consultation and secure medical file is combined into one Internet application.

The user accesses www.dokter.nl where a user can 'ask a doctor' a question. The online Dokter.nl triage system then refers the question to the appropriate specialist/doctor who is then notified through an e-mail and SMS. The specialist/doctor then accesses the secure user's medical file and answers the question which the user can then read. Where multiple questions are asked and answered the answers are stored in the user's file which allows the user to manage their own online medical files. All major medical specialties are represented in the dokter.nl team.⁵

(b) South African Examples

(i) 'Hello Doctor'⁶

'Hello Doctor' is a South African initiative providing medical guidance and advice to South African residents and visitors through and on its online platform. It was launched in 2010 as an attempt to address the socio-economic, political and technological advances that have taken place in South Africa and globally.

The initial service was a telemedicine model where a doctor would help a patient over the telephone by following a strict set of defined clinical digital triage and conservative parameters in giving advice and diagnosis. Where the doctor was unable to assist, the patient was to be referred to a participating 'pharmacy clinic' where the resident nurse could act as the 'eyes and ears' of the doctor (the so-called 'physician extender') thereby assisting the doctor in making an accurate diagnosis. While only clearly defined and strictly adhered to in-house protocols were established and adhered to by 'Hello Doctor' doctors with regard to what conditions could be treated. All other conditions were referred to the nearest clinic or medical facility. In May 2011 the HPCSA condemned this model as being unethical as no guidelines for telemedicine were in place but were 'currently being considered'.⁷

⁵WJPM Calis PHM Mulder 'Dokter.nl Digital Consultation' 2006 *Med-e-Tel* 85 -86.

⁶See [hellodoctor.co.za](http://www.hellodoctor.co.za) <<http://www.hellodoctor.co.za>>

⁷HPCSA Media Statement 'HPCSA condemns unethical telemedicine practice' May 2011 Available at <http://www.hpcsa.co.za/downloads/press_releases/current/hpcsa_condemns_unethical_telemedicine_p

Until such guidelines are in place and the 'unethical' nature of e-health has been established and clarified by the HCSA, 'Hello Doctor' has revised its service offering to focus only on preventative and educational health care and early disease detection.

'Hello Doctor' allows users to obtain online information about medical conditions, symptoms and care. It provides an opportunity for users to communicate to a qualified medical professional either via the 'Hello Doctor' website or telephonically and to participate in doctor-controlled chats and community health forums. In addition users can obtain contact details of their nearest doctor, hospital, clinic or pharmacy. It also provides wellness advice and health tips on various social media platforms such as Facebook, Twitter and MXIT.

The 'Hello Doctor' initiative acknowledges that not all medical conditions can be addressed or diagnosed over the Internet or telephonically and the applications may therefore not be appropriate for some medical conditions. It therefore limits its application to primary health care services and a specifically prescribed list of medical conditions. It further has developed minimum procedures, processes and clinical protocols to be followed in each session with an overriding warning to the doctors that if there is any doubt or concerns the session should not proceed and patients should be referred to a traditional medical facility.

As such 'Hello Doctor' does not provide diagnosis or on-line prescriptions but is primarily a forum for advice, information and appropriate referral. The 'Hello Doctor' initiative is a platform for exchanging health care information across distances mainly focusing on primary health care advice.

Despite the condemnation of the HPCSA, 'Hello Doctor' can be considered a conservative approach to online health care when compared to the social media applications found currently in Europe and the United States.

(ii) 'Cell-Life'⁸

Cell-Life is an example of the use of m-health in the management of HIV/AIDS treatment in South Africa. Cell-Life is a Cape Town based, non-profit organisation providing health management solutions via mobile devices and the Internet to

ractice.pdf>Accessed 1 February 2013 and C Bateman 'Cutting-edge telemedicine venture freezes as official bodies frown' (2011) 10 (6) *SAMJ* 368-372.

⁸Cell-life.org <<http://www.cell-life.org>> accessed 12 January 2013.

developing countries. Their intention is to distribute anti-retroviral treatments, monitor and evaluate HIV/AIDS patients and collect information pertaining to such patients. The project focuses on the management of the HIV/AIDS epidemic in South Africa. Sub-Saharan Africa has the highest incidence of HIV/AIDS in the world⁹ with South Africa as at 2011 having approximately 5.6 million people infected with the HIV/AIDS virus.¹⁰

As the majority of people living with HIV/AIDS in South Africa are resident in rural areas where there is often a lack of basic amenities, large patient volumes, staff shortages and an unreliable supply of anti-retroviral drugs to these centres. As a solution Cell-Life provides relevant information and access to communication facilities for the support of these people.¹¹

Cell-Life was initially a research collaboration between staff of the Engineering Faculties at the University of Cape Town and the Cape Peninsula University of Technology. It started as a community home-based care system for the management of HIV/AIDS patients based on the desire to support primary health care in South Africa. It has subsequently been expanded to cover other aspects of the HIV/AIDS management process, for example, pharmacy stock control, counselling, education and HIV testing.

Open source software applications and cellular technology were combined to create an m-health platform that is used to by health workers to access HIV/AIDS patients' health and anti-retroviral treatment records. Information, including drug dosage and side effects, is then collected by the health worker who is responsible for and oversees the HIV/AIDS patient. This information is sent to a central database for analysis by a care manager who then provides feedback to the health worker and who communicates it to the patient.¹²

⁹69% of the global HIV/AIDS population, UNAIDS report on the Global Aids Epidemic, 2012

¹⁰UNAIDS Available at <<http://www.unaids.org/en/regionscountries/countries/southafrica/>> Accessed 23 January 2013

¹¹R Wootton NG Patil RE Scott and K Ho *Telehealth in the Developing World* 2009 Royal Society of Medicine Press Ltd 46 Available at <http://www.ghdonline.org/uploads/Telehealth_in_the_Developing_World_2012_1.pdf> Accessed 10 February 2013.

¹²M Mars and C Seebregts 'Country Case Study for e-Health: South Africa' 2008 Rockefeller Foundation Available at <<http://www.ehealth-connection.org/content/country-case-studies>> Accessed 23 January 2013

V. CHAPTER 5 : REGULATIONS

(a) The law of the horse and why e-health poses a challenge to the regulators

That e-health has the potential to transform health care practice and the interaction between health care practitioners and patients is undoubtedly beyond question.¹ Most if not all health care practitioners have at some time, albeit unwittingly, practiced e-health by for instance giving medical advice to a patient or fellow health care practitioner over the telephone.² What is less clear is how the regulators propose to deal with its emergence.

The task of developing regulations is made more complicated by the multifarious conflicting commercial and humanitarian policy considerations which require careful balancing. There is a clear need to integrate e-health with e-commerce while not compromising the fundamentals of human and consumer rights and medical ethics.

It was suggested by Judge Frank Easterbrook at a conference at the University of Chicago on the 'Law of Cyberspace' that the most advantageous way to learn the law applicable to a specialised endeavour was to study and apply general rules.³ Easterbrook saw no urgency in harmonising either the procedural or substantive Internet law. He argued that 'internet law is nothing more than everyday cases whose only common element is the incidental use of a new technology'. In Easterbrook's opinion, 'devoting time and effort to studying "the law of the Internet" makes as much (or as little) sense as studying 'the law of the horse.' He explained that, '[l]ots of cases deal with sales of horses; others deal with people kicked by horses; still more deal with the licensing and racing of horses, or with the care veterinarians give to horses, or with prizes at horse shows. Any effort to collect these strands into a course on 'The Law of the Horse' is doomed to be shallow and to miss unifying principles.' Rather he suggested that 'only by putting the law of the horse in the context of broader rules about commercial endeavors could one really understand the *law* about horses'.

¹K Poe 'Telemedicine liability: Texas and other states delve into the uncertainties of health care delivery via advanced communications technology' (2001) 20 *The Review of Litigation* 681.

²C Jack and M Mars 'Telemedicine a need for ethical and legal guidelines in South Africa' (2008) 50(2) *South African Family Practice* 60a and B Stanberry 'Telemedicine: Barriers and opportunities in the 21st century' (2000) 247 *Journal of Internal Med* 615 at 628.

³FH Easterbrook 'Cyberspace and the Law of the Horse' 1996 *University of Chicago Law Forum* 207.

Easterbrook's advice to simply ignore cyberspace law, is seen by critics as unrealistic in the borderless Internet environment.⁴ It is suggested that to 'simply enjoy the benefits of cyberspace without participating in global Internet law harmonisation' is problematic and unachievable. The suggestion is rather than struggling to adapt an imperfect legal system to a developing world, we should allow the participants in the emerging, evolving world of cyber law greater participation in making and finding relevant and workable solutions.⁵

Similarly there is a debate as to whether a separate category of law should be created to accommodate e-health. The primary debate centres on whether there is any merit in regulators, health practitioners and users of e-health using the law as it currently stands and only addressing any legislative shortcomings that may be identified. Is a specific requirement for effective regulation of online activity necessary or do traditional common law principles as well as the rights entrenched in the Constitutional provide adequately for the fast developing online environment? Is our existing common law sufficiently comprehensive to cater for activities on the Internet or is it necessary to provide separate regulations and legislation tailor-made for Internet activities?⁶

It may not be entirely plausible to establish a regulatory framework separate from that which is currently in existence. Much of the existing and proposed South African legislation, for instance, the privacy and confidentiality provisions and protection of personal information provisions contained in POPI, are inter-dependent and may well be married within an e-health regulatory framework. However, greater clinical processes and protocols are recommended to reduce some of the risks associated with the practice of e-health.

(b) Regulation of social media : Is it even possible?

The Leveson Report published in the United Kingdom in November 2012 noted that the online social media world remains 'beyond regulation'. Describing the insurgence

⁴L Lessig 'The law of the horse: What cyber law might teach' 1999 *Harvard Law Review* 501 at 502.

⁵Easterbrook op cit note 3 at 207.

⁶Cyberpaternalism argues that the Internet is best regulated by the same rules and regulations that are applied in the physical world, See 'The development of a new model of governance for online defamation in light of the emergence of social web technologies' Available at <www2012.wwwconference.org/proceedings/nocompanion/wwwwebsci2012_khan.pdf>

of the social media as ‘little short of phenomenal’ the report acknowledges that websites were ‘entirely unregulated’ and that this situation was ‘unlikely to change’. The report states that ‘[d]espite the efforts made to comply with national law, it is clear that the enforcement of law and regulation online is problematic’.⁷

The difficulty with regard to social media regulations, is that the Internet is largely ubiquitous, not defined by any borders or boundaries, and is consequently almost impossible to regulate in any meaningful way. Collier questions whether the Internet should be viewed as a distinct location for the purposes of regulation - as a ‘fourth international space’ or a ‘distinct place’.⁸ It is suggested that this could assist in issues of jurisdiction and choice of law. The Internet would then be regulated by treaty and would be binding on all countries who are signatories thereto. Alternatively, it is suggested that the Internet could be defined ‘by new boundaries’ that can simplify and clarify the regulations applicable to the Internet and ‘create new law and legal institutions of its own, a so-called “law of Cyberspace”’. This, it is suggested, could go some way in simplifying matters cross jurisdictionally and internationally - whether these options are in fact feasible remains to be seen.

(c) A word on the regulation of online content

There is currently no legislation in South Africa regulating content on the Internet. Recent policy developments internationally are however indicating a general trend recognising the need for the regulation of content.

While acknowledging the negative effects of harmful content, regulating content goes against the very philosophy of the Internet, which is based on the free and open flow of ideas and information. As deciding what content is acceptable and what is not is based on a value judgement, the dilemma is that in protecting and safeguarding users, and still promoting the free and open flow of information, the

⁷Leveson Inquiry on Twitter and Facebook: Social media World remains ‘beyond regulation’ Huffington Post UK posted 29 November 2012 Available at http://www.huffingtonpost.co.uk/2012/11/29/leveson-social-media-online-blogs-law-press_n_2212597.html Accessed 15 February 2013 and The Leveson Inquiry ‘Culture, practices and the ethics of the press’ Available at <http://www.official-documents.gov.uk/document/hc1213/hc07/0780/0780.asp> Accessed 15 February 2013.

⁸L Lessig ‘The law of the horse: What cyber law might teach’ 1999 *Harvard Law Review* 501 at 505 and D Collier ‘Freedom of Expression In Cyberspace: Real Limits In A Virtual Domain’ (2005) 1 *SLR* 20 at 26.

service provider or web site owner assumes the role of a private censor which is undesirable.

Legal regulation of the Internet remains a grey area. If a service provider removes material from a website simply because someone objects to it or claims it be undesirable it may create a situation where individuals can force a service provider to remove content on demand. It seems unacceptable that an offended party should simply be able to notify a service provider and compel the service provider to act. The difficulty being that in trying to protect the offended party, the service providers may still face legal action by the supposed offender on the grounds that their right to freedom of expression has been violated.

Social media such as websites, blogs, tweets, wikis and social network platforms primarily open up and encourage widespread and dynamic communication channels. What is clear is that as the world increases in online exchanges and more frequent electronic commercial transactions, it is certain that more auto-regulatory rules and strategies will be enacted to protect against uses and abuses of the Internet. Perhaps similar technologies could be useful in the future to regulate undesirable or misleading content on the Internet.

It is suggested that an appropriate approach with regard to online content would be to adopt a regulatory model 'whereby the pro-human value of social web technologies is not lost but allowed to flourish; rather than forcing technology to regress to the wants of the law, the law and governance are forced to evolve so as to allow the benefit of social web technologies to continue'.⁹

(d) Is the South African approach to health care regulations adequate considering recent developments in other jurisdictions?

With progressive developments in e-health it is relevant to look at the ethical implications of using e-health technology. By doing so, we can seek the optimal ways to attain the benefits of e-health in an ethical manner while avoiding potential pitfalls that may diminish the health care profession or be detrimental to patients.¹⁰ The

⁹'The development of a new model of governance for online defamation in light of the emergence of social web technologies' Available at <http://www2012.wwwconference.org/proceedings/nocompanion/wwwwebsci2012_khan.pdf>.

¹⁰Iserson, K 'Telemedicine: A proposal for an ethical code' (2000) 9 *Cambridge Quarterly Healthcare Ethics* 404.

thinking on regulation development by some is that an entirely new regulatory structure is needed to support the high-tech transformation to modern health care. Others disagree and recommend adapting law as need be while adopting a 'wait and see' approach.

While internationally, technical and operational standards¹¹ have been the driving focus in the creation of new regulations thus far, regrettably ethical guidelines have to a large extent been neglected.¹² Unfortunately, e-health regulations are being created in a 'parochial and nation-centric manner' as states develop e-health policies to suit their unique needs. This threatens to entrench what Mars and Scott describe as an e-health 'silo' mentality, so that 'instead of e-health leading to a borderless global environment, the developing world will be further isolated from the international benefits of global e-health'.¹³

(i) So-called 'glocal' approach

It is clear that the inherent nature of e-health which allows it to transcend borders and boundaries does not easily conform to national health systems or their laws.¹⁴ Trans-border e-health encounters are an issue of international concern.¹⁵ The term 'glocal' is a blend of the words 'global' and 'local' and has appeared in health literature recently. It describes the 'networked world' that is what occurs locally has a global impact and what occurs globally impacts on the local.¹⁶ This is of particular relevance to regulators and legislators who, when determining the way forward regarding health policy, are required to think globally while acting locally.¹⁷

The WHO has reported that 'the most favorable approach to the implementation of e-health at the national level is to have a framework of strategic

¹¹Technical standards contain the steps, protocols and describe information that should be used and implemented in any newly defined e-health legislative measures, codes of conduct, guidelines and regulations.

¹²Z Stapić N Vrček and G Hajdin 'Legislative Framework for Telemedicine' University of Zagreb, Croatia Available at <<http://www.ceciis.foi.hr/app/index.php/ceciis/2008/paper/view/74/90>> Accessed 8 February 2013.

¹³M Mars and RE Scott 'Global e-health policy: A work in progress' (2010) 29 2 *Health Affairs* 239 at 244.

¹⁴RE Scott, PA Jennett and M Yeo 'Access and authorisation in a glocal e-health policy context' (2004) 73 (3) *Int J Med Inform* 259–66.

¹⁵Mars and Scott op cit note 13 at 239.

¹⁶Ibid.

¹⁷Scott et al op cit note 14 at 259.

plans and policies which lay the foundations for development'.¹⁸ Although the 2006 WHO report calls for strategic plans and policies to ensure interoperability between telecommunication systems and to allow for all citizens to gain access to e-health solutions, it fails to provide for a so-called 'glocal' e-health development policy.¹⁹

However in the 2010 WHO report member states are encouraged to capitalise on the potential of ICTs by the 'creation of national agencies to coordinate telemedicine and e-health initiatives, ensuring they are appropriate to local contexts, cost-effective, consistently evaluated, and adequately funded as part of integrated health service delivery'. The conclusion found in the report is that e-health initiatives 'should strengthen – rather than compete with – other health services'.²⁰

(ii) International regulatory developments

To date international guidelines have been developed by the United States, United Kingdom, India and Australia.²¹ These guidelines focus primarily on clinical, operational and technical issues relating to e-health rather than dealing specifically with ethical issues.²²

The United States has made considerable financial investment into the development of telemedicine over the past few years.²³ In line with this the United States the American Telemedicine Association (ATA) has established practice and technical guidelines and standards for the field of telemedicine and e-health. The document entitled 'Core Standards for Telemedicine Operations' seeks to address clinical and technical standards for electronic communications between health practitioners and patients for the purposes of health care delivery. Ethical issues such as the protection of patient information and informed consent are addressed but only to the extent that they concern existing regulative or legal requirements.²⁴ Health

¹⁸Report of the WHO Global Observatory for E-health. Geneva: World Health Organisation; 2006.

¹⁹Mars and Scott op cit note 13 at 240.

²⁰WHO 'Telemedicine – Opportunities and developments in Member States' Global Observatory for e-health series vol 2 2010 Available at <http://www.who.int/goe/publications/goe_telemedicine_2010.pdf> Accessed 1 February 2013.

²¹Jack and Mars op cit note 2 at 60b.

²²Ibid.

²³Stapić et al op cit note 12.

²⁴The American Telemedicine Association's Guidelines – core standards for telemedicine operations 2007 Available at <http://www.ict-ageing.eu/?page_id=1291> Accessed 1 February 2013.

practitioner societies and academic-based organisations in the United States played a collaborative role in the development of the e-health industry guidelines.²⁵

Malaysia is proactive in the development of both legislation and guidelines for e-health. It is one of the few countries that regulate the practice of telemedicine or issue certificates for this purpose through legislation. However, the introduction of regulations by Malaysian authorities albeit for domestic purposes, has had a restrictive effect on global e-health activities.²⁶

In Europe 'Telescope' an organisation funded by the European Commission has undertaken to develop a comprehensive Code of Practice for Telehealth Services.²⁷ The objective of Telescope is to develop a code of practice and to support the Communication from the EU commission on telemedicine for the benefit of patients, health care systems and society (EC COM2008:689) to 'improve confidence in and acceptance of telemedicine'. The code of practice recognises the requirement set out in EC COM2008:689 to integrate e-health into member states health care systems and endeavours to deploy good practice in the provision of e-health services. It also seeks to address the issues of accreditation, privacy and data protection.²⁸

Likewise in the United Kingdom and Australia, private organisations such as Telecare Services Association UK²⁹, as well as the Australian government's IT-014-12 Telehealth standards subcommittee³⁰ and the Royal Australian College of General

²⁵R Friedberg 'Is Telemedicine a Fundamentally Different Way of Practicing Medicine?' Available at <<http://www.techhealthperspectives.com/2012/06/06/is-telemedicine-a-fundamentally-different-way-of-practicing-medicine/>> Accessed 1 February 2013.

²⁶Mars and Scott op cit note 13 at 242. The section entitled 'Teleconsultation Beyond National Borders' states that '[p]atients and health care professionals should be provided the opportunity to seek an expert opinion and treatment from overseas through teleconsultation'. But then proceeds to state that '[f]oreign experts can provide teleconsultation to health care professionals and/or patients in Malaysia only at the invitation of the local health care personnel' and '[a]ll overseas experts who are invited to provide opinion or who are referred cases must be registered with the appropriate regulatory authorities in Malaysia' with penalties for non-compliance including fines and imprisonment. It is suggested that regulations of this sought are problematic and raises 'potential administrative barriers to borderless global e-health initiatives'.

²⁷Available at <<http://www.telehealthcode.eu/>> Accessed 31 January 2013

²⁸Commission of the European Communities 'Communication from the Commission to the European Parliament on telemedicine for the benefit of patients, health care systems and society' Available at <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF>> Accessed 30 January 2013.

²⁹Available at <<http://www.telecare.org.uk/>> Accessed 1 February 2013

³⁰Available at <<http://www.ehealthstandards.org.au/IT014SubjectAreas/Telehealth.aspx>> Accessed 1 February 2013.

Practitioners³¹ are in the process of developing clinical guidelines and standardised codes of practice for the e-health industry.

The World Medical Association has developed ethical guidelines on telemedicine. Similarly an e-health Code of Ethics was drafted in 2000 setting out guiding principles such as quality; informed consent, privacy, professionalism in online health care, responsible partnering and accountability. The intention was to ensure that people using the Internet to manage health care could do so confidently and with full knowledge of the risks involved.³²

(iii) How does South Africa fare in light of international developments?

South African regulators intend addressing the ethical challenges presented by e-health by regulation. This is based on the premise that patients are at risk and need protection by regulation.

The HPCSA has drafted the proposed 'General Ethical Guidelines for Good Practice in Telemedicine'. This sets out clinical, operational and ethical guidelines that should be adhered to by the governing bodies or associations of the various clinical disciplines using e-health in the provision of health care. The HPCSA proposes that a regulated e-health environment would ensure the quality of health care delivery for South Africans. The proposed guidelines however fail to adequately address the fundamental challenges concerning e-health in a developing country or to provide any meaningful, workable solutions. The HPCSA appears to be grappling with the very idea that e-health, in various forms, is here to stay and that comprehensive, consultative participation is necessary from all stakeholders.

Moreover, the HPCSA's prohibiting the practice of e-health in certain sectors based on ethical uncertainty³³ constitutes a de facto moratorium against its practice that flies in the face of any efforts to integrate it into the health care system and to reap its potential benefits. That being said it is not suggested that unfettered practice should be allowed but rather that the authorities adequately apply their minds to the facts and

³¹Available at
<http://www.racgp.org.au/download/documents/Standards/standards4thed_keychanges.pdf> Accessed 1 February 2013.

³²H Rippen and A Risk 'e-Health Code of Ethics' (2000) 2 (2) *J Med Internet Res* e2.

³³HPCSA Media Statement 'HPCSA condemns unethical telemedicine practice' May 2011 Available at
<http://www.hpcsa.co.za/downloads/press_releases/current/hpcsa_condemns_unethical_telemedicine_practice.pdf> Accessed 1 February 2013.

establish clearly defined and suitable parameters within which e-health applications can operate lawfully and ethically.

Pivotal to this is whether it is even relevant to regulate e-health in developing countries at all.³⁴ In light of the pressing problems inherent in health care provision faced by developing countries today, are different, less restrictive ethical and clinical guidelines and standards of care for e-health warranted from those implemented in developed countries. Whether this compromise is too high a price to pay or whether it will streamline an efficient and cost effective health care alternative remains to be seen.

While it cannot be denied that there are potential risks involved in e-health and that states have obligations to protect their citizens from potential harm by putting in place laws and regulations which ensure their protection, what seems inconceivable is that a child in a rural area of the country for example should be denied access to a doctor telephonically for treatment and/or advice to treat a condition simply because there is no face-to-face consultation. Although there is a reluctance to change, it is suggested that for the treatment of certain, appropriate medical conditions and more particularly in the provision of primary health care, when conducted within clearly defined parameters, there is no reason why a telephonic or online consultation with a health care professional cannot offer an ethical and workable solution.

Can it be said that in developing countries, as long as there is no compromise in an acceptable and appropriate standard of care, some health service is preferable to no health care service at all, even if such health care may not necessarily meet the stringent standards of the developed world?³⁵ More pointedly, is the unproven and unidentified threat of potentially harming patients through sanctioning the use of e-health justified to the extent that in refusing such care it violates the human rights of its people in a more immediate and severe way by depriving them of the only source of health care available and for some of them perhaps certain death? It seems unlikely that such an approach should be justifiable in a humanitarian crisis such as that which faces Africa today.

Despite the repeated call for ethical guidelines regarding e-health and telemedicine services, no ethical guidelines have as yet been developed in South

³⁴M Mars and C Jack 'Why is telemedicine a challenge to the regulators? (2010) 3 (2) *SAJBL* 55- 58.

³⁵Jack and Mars op cit note 2 at 60a.

Africa.³⁶ Sadly, a legal position of vague, unclearly defined provisions together with an avoidance and reluctance to comprehensively and holistically address the issues regarding e-health can only be detrimental and is a situation in need of reform.

(e) How should regulation be approached in South Africa?

Whereas e-health policy in developed countries focus on issues of information security, content quality and accuracy, licensure, confidentiality and privacy, 'developing countries are in danger of being led, unwittingly, into adopting so-called international best practices, which may well be inappropriate for the developing world'.³⁷ It is suggested that regulatory authorities should:

(i) Provide regulation that is enabling and contextually appropriate

E-health practitioners and developers need greater clarity and certainty of their legal and ethical roles and responsibilities in the practicing of e-health. Similarly, users and patients require protection with regard to standards of care and the assurance of being safely treated by properly qualified practitioners. Legislation and regulations that are enabling, progressive and contextually appropriate are needed.

(ii) More carefully define the concept of e-health and what it means to 'practice' medicine

E-health is multi-faceted and dynamic and spans a broad and full spectrum of activities and disciplines. The definition should consider all aspects and applications of e-health (not just the traditional concept of 'telemedicine').

(iii) Avoid a 'one-size fits all approach'

³⁶Ibid at 60b.

³⁷Mars and Scott op cit note 13 at 243.

A 'one-size-fits-all' approach to e-health implementation and regulation is not only impractical but also undesirable.³⁸ E-health covers such a wide array of practices across various disciplines, using different platforms that are constantly evolving that regulations have to be carefully and contextually drafted and implemented to cater for a constantly changing and divided world. It is suggested that a degree of legal flexibility is required to accommodate these challenges, making the 'one-size-fits-all' approach of standardising and harmonising international regulations and applying them to a South African context not entirely feasible.

(iv) Following a 'glocal' approach

Given that the requirements, issues and focus of the developed world differs to a large extent from those that may be considered relevant in developing countries, regulations appropriate for the developed world may not be entirely appropriate or compatible in the developing world. The difficulty in formulating 'international best practices' for the developing world, it is suggested, is that it may lead to a further deepening of the 'digital divide' between the developed and the developing world. It is suggested that one should rather approach the formation of regulations in a 'glocal' way, that is, to create e-health policy 'tailored to the specific needs of a given locality and population' with due consideration to global implications and influences.³⁹

(v) Establishment of a national e-health agency

The WHO recommends that national and international agencies should be used 'to help define the vision and objectives of national telemedicine policies and direct efforts towards implementation within countries'.⁴⁰ Unfortunately the situation at present is that only 30% of countries reported having a national agency for the development of e-health, with only 20% reported having 'developed and implemented a national telemedicine policy'. Based on these findings the WHO calls for member

³⁸N Friederici, C Hullin and M Yamamichi 'm-Health' *ICD: maximising mobile* 2012 45 at 52 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

³⁹Mars and Scott op cit note 13 at 243.

⁴⁰WHO 'Telemedicine – Opportunities and developments in Member States' Global Observatory for e-Health series vol 2 2010 Available at <http://www.who.int/goe/publications/goe_telemedicine_2010.pdf> Accessed 1 February 2013.

states to prioritise the establishment of a national e-health agency ‘to guide a strategy for the development, implementation, and evaluation of e-health solutions’.

(vi) Engagement in greater collaboration with international agencies

It is further suggested by the WHO that a collaborative approach between regulators, health administrators, health professionals, academic institutions and communities be implemented - by doing so e-health would find its recognised place within the current health system. It is also envisaged that those working within a specific region or community 'would be best positioned to understand specific regional or national clinical approaches, legal frameworks, and cultural approaches to health services delivery'. Greater collaboration with international institutions⁴¹ would also ensure that 'innovative ideas and practices brought from outside the local context could be introduced and integrated with local support'.⁴² To the extent that it is appropriate the regulators should seek to standardise and harmonise legal policy on a national and an international level. Certainly, keeping abreast of developments and progress in international regulations and policy-making could provide potential leverage for national authorities.

(vii) Encourage engagement with all national stakeholders

Although largely the domain of the private sector, online health software applications are typically developed by a host of different role-players, including software developers, content providers, device manufacturers and users, with non-governmental organisations (NGOs) playing a potentially important role in customising applications to meet the requirements of local communities.⁴³ This collaboration is becoming increasing prevalent in the development of e-health services and the regulators need to provide an environment which is encouraging of co-operation between the various

⁴¹International agencies such as mHealth Alliance, the Health Metrics Network, and the Continua Health Alliance are in the process of developing globally recognised standards and metrics especially relevant for instance in the storage and transmission of electronic health records.

⁴²WHO Global Observatory for e-health series op cit note 40.

⁴³World Bank 'Information and communications for development: maximizing mobile' 2012 at 4 Available at <<http://www.worldbank.org/ict/IC4D2012>> Accessed 8 February 2013.

stakeholders.⁴⁴ While it is suggested in the World Bank report that 'a push for more universal platforms' can either come from the top, that is, government, 'as part of a national e-health strategy that encompasses m-health', or from the bottom, that is the developer or users, it is suggested that the 'greatest value will be realised when both strategies are used and complement each other'.⁴⁵

(viii) Embrace private sector e-health initiatives and cooperation between the public and private sectors

While health care implies a public sector involvement, there is potential in private sector e-health initiatives suggesting that hybrid models may be an appropriate option. It is suggested that barriers to e-health development be reduced by building on existing resources and infrastructure. In addition, regulatory authorities should address the lack of sustainable e-health business models and encourage the roll out of privately owned m-health and e-health products and services. Greater co-operation and collaboration between the public and private sectors should be sought and clear, acceptable business models for the purposes of conducting an e-health professional practice or platform should be identified.

(ix) Facilitate the granting of licences to practice e-health

Regulations should encourage the appropriate oversight, credentialing and licensing of e-health practitioners across jurisdictions and facilitate the creation of reciprocity and recognition agreements between countries for easier cross border practice.⁴⁶

(x) Consider the changing nature of the socio-cultural environment

⁴⁴An example of co-operation between the state, research institutions and the private sector with regard to health care delivery may be found in the Free State community of Botshabelo where in 2009 it was one of the first beneficiaries of four PHC telemedicine workstations developed by the South African Medical Research Council (MRC) and Stellenbosch University under a DST/National Research Foundation Innovation Fund award. The project was also supported by the MTN SA Foundation, which provided increased bandwidth. See in this regard N Bhagwandin 'Health Technology for equitable access to quality health services' (2011) 8 *SAHR* 96.

⁴⁵Friederici op cit note 38 at 50.

⁴⁶Iserson, K 'Telemedicine: A proposal for an ethical code' (2000) 9 *Cambridge Quarterly Healthcare Ethics* 404.

The social-cultural environments within which e-health is practiced is constantly changing, in light of this regulations need to be suitably adaptable to accommodate a progressive and evolving industry. The e-health industry may evolve in ways that cannot be anticipated so a degree of flexibility may be required.⁴⁷ By investing in e-health applications, public health issues, for instance, in the education and support of the prevention of non-communicable diseases, would not only assist in the reduction of health care costs in the community but also guarantee a healthier and productive workforce for developing economies.⁴⁸

(xi) Establish a task team to oversee regulatory transformation

It is suggested that a task team reporting to the South African Ministry of Health, comprising suitable representatives from clinical, judicial, ethical, technological and commercial disciplines representing both the public and private interests be established to champion and fast-track the process of e-health regulatory transformation in South Africa. A consolidated approach with a clear set of objectives, deliverables and delivery dates would ensure that the development of guidelines and regulatory review is not only achievable but is actually implemented.

(xii) Ensure quality and content of health information

(xiii) Safeguard users' right to be the owner of their information and ensure adequate data security, protection and privacy laws are in place.

(xiv) Encourage and find appropriate alternative, more pragmatic methods of performing activities in a virtual environment so that they have the same effect as those done using traditional methods

The ECT Act certainly does this by means of introducing the concept of an electronic contract into the legal system. Electronic documents are afforded the same weight as traditional, paper equivalents. This should be extended to other interactions in the e-health environment where virtual equivalents are considered analogous to 'real'

⁴⁷Friederici op cit note 38 at 53.

⁴⁸Ibid.

interactions, such as the requirement for signed, written informed consent⁴⁹ and the need for face-to-face consultations and ‘physical’ examinations.

University of Cape Town

⁴⁹Professor M Mars quoted in C Bateman ‘Cutting-edge telemedicine venture freezes as official bodies frown’ (2011) 10 (6) *SAMJ* 368 at 372.

VI. CHAPTER 6: RECOMMENDATIONS AND CONCLUSION

(a) Is South Africa doing anything right?

Health care reforms centre on improving performance. To create a health care system that is more productive and effective, a search for alternative transformative service delivery methods embracing the introduction of new technologies and e-health methodologies is needed.¹

A firm commitment and clearly articulated stance by the SA government to the introduction and utilisation of e-health as an integral component to health care service delivery has been provided in the roll-out of the government's envisaged multibillion rand National Healthcare Insurance (NHI) initiative.² Although the government's commitment is apparent, a fragmented approach to e-health policy development, combined with a haphazard decision-making and implementation process only impedes the progress of e-health delivery. The effective procurement, utilisation and maintenance of e-health technologies will require considerable financial, organisational and human resources investment which by implication will necessitate a very definite and clear multi-disciplinary e-health strategy. A task which although challenging, is not impossible to achieve.

By subscribing to various international instruments South Africa has aligned itself to various international positions regarding e-health which is to be welcomed. This will pave the way for a consolidated and comparative perspective in order to fully analyse the sufficiency of SA's legal regulatory system for e-health within a global context.

South Africa has more incentive than just its international law commitments to develop e-health. The most important obligation the South African government has in relation to creating national e-health regulatory measures is upholding the right to health commitment contained in its Constitution. The current legislative position

¹L Schoeman 'Embracing e-government: in search of accountable and efficient governance objectives that improve service delivery in the South African health sector' (2007) 42 (5) *Journal of Public Administration* 183 at 184.

²R Weeks 'A technology perspective of health care services management' (2012) 12 *Acta Commercii* 173.

regarding electronic transactions in the ECT Act, privacy legislation contained in POPI and the access to information in PAI Act can be considered a step in the right direction. However, a patchwork approach to e-health legislation and regulations may not be ideal.

(b) Where to from here?

Technologies often precede the development of laws on how to use them, and this certainly appears to be the case with e-health regulation in South Africa. Rather, than shying away, greater public accountability in the health care sector is called for with government rising to the challenge.

It is suggested that the strategy for the way forward should be one of the following approaches.

- The continued development of ad hoc regulations and policy realignment as and when the situation requires. This is the current unclear and seemingly unfocused position and prevents a streamlined global approach to e-health. It is suggested that to adopt this approach in the consolidation of retrospective policy realignment to bring about disparate approaches together would take time and in the interim, the potential benefits of global e-health will be lost.
- A progressive and collaborative complementary regulatory development strategy it is suggested would be a more beneficial approach. Such an approach would capitalise on and realise the benefits of global e-health sooner. It is suggested that the strategy would be to identify common principles and issues that can be easily agreed upon, and then to ‘use these to encourage development of domestic policy that is in line with global e-health principles’. This would in turn remove administrative and political barriers to global e-health.³

In South Africa progressive, enabling legislation within a uniquely South African context is called for. This should be done in collaboration with all relevant stakeholders. Regulation development in South Africa would necessitate the creation

³R Wootton, NG Patil and RE Scott K Ho *Telehealth in the Developing World* 2009 Royal Society of Medicine Press Ltd 65 Available at <
http://www.ghdonline.org/uploads/Telehealth_in_the_Developing_World_2012_1.pdf> Accessed 10 February 2013.

of an inclusive and 'glocal' process and a more pragmatic approach to issues such as written consent, prior doctor-patient relationship and licensure.⁴

It is suggested that any deficiencies in existing guidelines and regulations should be identified and thereafter clinical, operational and ethical guidelines should be developed to cover any shortfall if required. This should be done with greater consultation and collaboration of the governing bodies or associations of the various clinical disciplines. As e-health develops all the gaps need to be closed and in so doing further discussion and consultation on the subject is required. This should involve greater collaboration between all stakeholders while taking cognisance of the fact that a 'one-size-fits-all' approach to e-health regulation is not appropriate.⁵

The issues regarding privacy and confidentiality are already in place in existing health and other legislation, however the consent requirements should be extended and adapted to an online environment. Finally, the HPCSA it is felt should act within its powers by focusing in a way that protect the user/patient and at the same time be progressive and enabling in the creation of its guidelines. Only then can we hope to realise the benefits of e-health in South Africa in any constructive way.

(c) Conclusion

Telemedicine and e-health is advanced and practiced in many jurisdictions around the world including the United States, the European Union and the United Kingdom. These countries have all accepted the impact of technological development on modern medicine and the evolving patient-doctor relationship.

What is clear is that e-health in one form or another is undeniably here to stay and it is incumbent upon the regulators to provide and maintain legal certainty for health professionals and patients/users going forward. For e-health to succeed and be of benefit it requires a clear and enabling legislative and regulatory environment. There is little doubt that communication technology has the potential to revolutionise medical care and public health especially in developing countries such as South Africa.⁶ Despite a tension existing between traditional medical practice and e-health

⁴M Mars and C Jack 'Why is telemedicine a challenge to the regulators?' (2010) 3 (2) *SAJBL* 55 at 58.

⁵M Kekana, B Mkhize and P Noe 'The practice of telemedicine and challenges to the regulatory authorities' (2010) 3(1) *South African Journal of Bioethics and Law* 33 at 34.

⁶Wootton et al op cit note 3 at 55.

applications, it is necessary to incorporate e-health into the existing system and for e-health to find its rightful place. With the rise of international awareness, greater consumerism, patient empowerment and the use of technology the way health care is provided and consequently, legal systems and regulations, are being challenged and undergoing reform. How this will translate into a changing world remains to be seen.

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