

Electronic health records: What measures health professionals can take to protect patient data?

By

Rakesh Mohanlal 872875597

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Supervisor: Professor DJ McQuoid-Mason

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Declaration of Candidate

This research has not been previously accepted for any degree and is not being currently considered for any other degree at any other university.

I declare that this Dissertation contains my own work except where specifically acknowledged.

Rakesh Mohanlal - 872875597

Signed _____

Date 24 July 2017

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Obstacles are mere perceptions that are created in our own minds. If one lives life in a 'goal orientated' blissful state and dream of achieving the impossible, one will succeed.

Abstract

Electronic health records use in South Africa is limited. Globally, increased efforts are being made to digitalise medical records into one interoperable system.. Due to the nature of the transmission and storage of such confidential information via electronic means, the issues of privacy, informed consent and the security of such systems have given rise to legal-ethical debate. Other issues such as ownership of such records and their security have not been entirely resolved. However, in both South Africa and internationally, it is accepted that negligent or unlawful disclosure of confidential medical information can violate a person's right to privacy and impair their dignity. The use of electronic means has been implicated in changing the doctor-patient relationship by adding business efficiencies such reliability, accuracy and speed. Other issues include whether additional contracts are required between the stakeholders when electronic health records and electronic means are used. Contractual terms such as the use of exemption clauses and the legal implications of use thereof need further consideration. Health records are an ancient art that has transcended into a contemporaneous record that can include various digital and electronic elements. Developed countries such as the United States of America and United Kingdom have more experience in the use of electronic health records systems and their associated security than places like South Africa. The academic literature thus focuses on the legal and ethical implications of electronic health records in these developed countries. A brief comparative analysis was undertaken of a few selected medical professional bodies in the United States and United Kingdom. A comprehensive evaluation was conducted of South African statutory law in relation to the use of electronic health records. The *Tshalabala-Msimang* case that discussed the theft and publication of health records provided the foundation for the development of measures for the use of electronic health records in South Africa. An evaluation of the Cybercrimes and Cyber Security Bill assisted in advocating a model of measures that can be employed when electronic health records are used.

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LIST OF ACRONYMS

ASSAL	Annual Survey of South African Law
BMC	BioMed Central
BOR	Bill of Rights
CC	Constitutional Court
CPA	Consumer Protection Act
CTOP	Choice of Termination of Pregnancy
ECHR	European Convention of Human Rights
ECTA	Electronic Communications and Transactions Act
EHR	Electronic health records
FDA	Food and Drug Administration
GMC	General Medical Council
HITECH	Health Information Technology for Economic and Clinical
.	Health
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
ICD	International Classification of Disease
IT	Information Technology
MPS	Medical Protection Society
MP	Medical Practitioner
MPs	Medical Practitioners
NHA	National Health Act
NHS	National Health Service
ONC	Office of the National Coordinator
PAIA	Promotion of Access to Information Act
POPI	Promotion of Access to Information
SA	South Africa
SCA	Supreme Court of Appeal
SALJ	South African Law Journal
SAJBL	South African Journal of Bioethics and Law
SAMJ	South African Medical Journal
Stell LR	Stellenbosch Law Review
THRHR	Tydskrif vir hedendaagse Romeins-Hollandse Reg

US

United States of America

WHO

World Health Organisation

CHAPTER ONE

‘Under the National Health Act, the employees have a statutory duty to “preserve and protect” hospital and medical records, and failure to comply opened them up to possible criminal prosecution, a fine or imprisonment. In addition, the Health Professions Council has set out guidelines for the keeping of patient records’ Pillay J.¹

1.1 Introduction and background

Health records are an essential part of a healthcare system and were traditionally stored in a paper-based format. Globally there is an increased trend to digitize this information. Digitization helps preserve and store the valuable data, and facilitates a cost-effective and efficient method of communication.² Technological progress allows a digital camera on a cellphone and other electronic features to record, compile, store and transmit personal information in a variety of ways and circumstances.³

The use of such electronic formats in the healthcare sector has been shown to improve quality, safety and efficiency, and to save costs.⁴ The World Health Organisation (WHO) has generally accepted electronic health records (EHR) as longitudinal health records with entries by medical professionals in multiple sites where care is provided.⁵ The use of e-commerce technology is recommended in healthcare, where EHR can be efficiently created, stored and accessed.⁶ As a result the global healthcare sector, including in developing countries such as South Africa (SA) is now operating in an electronic or digital environment.⁷ In the United States (US) EHR has been adopted at a rapid pace, spurred by dedicated legislation.⁸ The Health Information

¹ I Oellermann ‘Medical malpractice rife’ (15 March 2016) *The Witness* available at <http://www.news24.com/SouthAfrica/News/medical-malpractice-rife-20160314> accessed on 14 August 2016.

² PC Webster ‘CMA takes on electronic medical records’ (2015) 1187(15) *Canadian Medical Association Journal* E440.

³ J Burchell ‘The legal protection of privacy in South Africa: A transplantable hybrid’ (2009) 13(1) *Electronic Journal of Comparative Law* 1.

⁴ H Kluyts ‘Can information technology improve my ambulatory practice’ (2015) 21(1) *South African Journal of Anaesthesia and Analgesia* 59.

⁵ World Health Organisation ‘Electronic Health Records: Manual for Developing Countries’ (2006) available at <http://www.wpro.who.int/publications/docs/EHRmanual.pdf> accessed 14 April 2017.

⁶ Ibid.

⁷ Bradley et al ‘Digital Vortex: How digital disruption is redefining industries: an IMD and Cisco initiative’ (2015) available at http://www.imd.org/uupload/IMD.WebSite/DBT/Digital_Vortex_06182015.pdf accessed 5 March 2017.

⁸ See: Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. Hereafter referred to as HITECH. See also: A Wright ‘You, Me and the Computer Makes Three: Navigating the Doctor-Patient Relationship in the Age of Electronic Health Records’ (2015) 30(1) *Journal of General Internal Medicine* 1.

Technology for Economic and Clinical Health (HITECH) Act⁹ (US) introduced an incentive programme, referred to as ‘*meaningful use*’ that makes substantial financial payments to health professionals and hospitals that adopt EHR. While Inkosi Albert Luthuli Central Hospital in KwaZulu-Natal is currently the only paperless public hospital in SA, there are renewed efforts to expand the adoption and use of EHR to all state healthcare institutions.¹⁰ In August 2016, the government called for information technology (IT) companies to tender for a lucrative national electronic health record system.¹¹ The private healthcare sector has been more progressive in the introduction and use of this system.¹² Apart from these SA EHR initiatives there is no SA statutory equivalent to the US HITECH Act.

This research study focused on the legal-ethical dilemmas posed by the use of EHR and the experiences of a medical practitioner in the private sector.¹³ The primary legal and ethical concerns relating to EHR are that the information transmitted is private and poses a significant threat to confidentiality.¹⁴

1.2 The right to privacy, dignity, and electronic health records

Burchell argues that the right to privacy must be protected in the electronic era. He states that:

‘[I]f the law does not recognise the protection of individual privacy as a hallow right, a combination of government knee-jerk reactions to perceived terror threats and individual exploitation of intrusive potential of electronic communication and data capture might signal the demise of what little privacy we have.’¹⁵

⁹ Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act of 2009.

¹⁰ Health Systems Trust ‘Government paves the way for move towards paperless hospitals’ (2016) available at <http://www.hst.org.za/news/government-paves-way-move-paperless-hospitals> accessed 6 September 2016.

¹¹ Ibid.

¹² See: Discovery ‘HealthID: The technology that puts your patients’ health records in your hands’ (2016) available at <https://www.discovery.co.za/portal/individual/health-id> accessed on 5th April 2017. A medical aid administrator in SA introduced an EHR system that is in operation. MPs are incentivised with an enhanced consultation fee for the use of the EHR system, presenting and witnessing the signing of the electronic HER contract.

¹³ The writer is a qualified medical practitioner in private practice with more than 20 years’ experience in the field of family medicine and holds the following qualifications MBCh (Wits) ABP (DUT) BTech (DUT) LLB (UKZN) MBA.

¹⁴ Burchell *op cit* 1.

¹⁵ Ibid.

Burchell quotes the European Court of Human Rights case of *Copland v United Kingdom*¹⁶ that held that telephone calls and e-mails from a business fell under private life and correspondence.¹⁷ In this instance the court held that monitoring such communications constituted a breach of Article 8 of the European Convention of Human Rights (ECHR). He adds that in an electronic era, privacy and dignity are facets of a person's personality that are part of their humanity and are worthy of protection by the law of delict.¹⁸ Writers such as Neethling et al have also argued for the worthiness of protection of privacy as an independent personality right.¹⁹

Prior to the electronic era, the Appellate Division of the SA courts recognized in the case of *Jansen van Vuuren v Kruger*²⁰ that privacy was worthy of protection as an independent right. In this instance a patient's HIV status was held to be worthy of protection. However, modern recently, numerous authors have argued that legal and ethical knowledge of EHR, including privacy and dignity rights, is incomplete.²¹

Thus, the main objective of this study is to expand on current legal and ethical knowledge in this area and that of informed consent when EHR are disclosed via electronic means. In SA the right to privacy is legally protected by three main sources, the Bill of Rights (BOR)²² in the Constitution²³, the common law, usually the law of delict, and legislation.²⁴

The fact that the constitutional right to privacy²⁵ and dignity²⁶ that is part of the BOR is legal protection is reflected in numerous Constitutional Court judgements.²⁷ In *NM*

¹⁶ *Copland v United Kingdom* [2007] ECHR 253.

¹⁷ Burchell *op cit* 1.

¹⁸ *Ibid.*

¹⁹ J Neethling JM Potgieter & JC Knobel *Neethling-Potgieter -Visser : Law of Delict* 6th edition (2010) 18-19.

²⁰ 1993 (4) SA 842 (A).

²¹ Wright *op cit* 1.

²² The Constitution of the Republic of South Africa, 1996, section 14 of the Bill of Rights, hereafter Bill of Rights referred to as the BOR.

²³ The Constitution of the Republic of South Africa, 1996, section 10.

²⁴ Burchell *op cit* 4.

²⁵ The Constitution of the Republic of South Africa, 1996, section 14.

²⁶ The Constitution of the Republic of South Africa, 1996, section 10.

²⁷ See: *NM and Others v Smith and Other* 2007 (5) SA 250 (CC), Hereafter referred to as *NM and Other*. See also: *Mistry v Interim Medical and Dental Council of South Africa* 1998 (4) SA 1127 (CC), hereafter referred to as *Mistry*. See further: *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A).

*and Others v Smith and Others*²⁸, O'Regan J offered a detailed consideration of the meaning of privacy. She described 'privacy, liberty and dignity as the key constitutional rights which construct our understanding of what it means to be a human being'²⁹ and affirmed that privacy is protected under dignitas.³⁰

However, O'Regan J noted that privacy was not an absolute right and had to be balanced against the right to freedom of expression³¹ in this case.³² She emphasised that this enhances human dignity and autonomy and makes democracy a reality.³³ In light of this argument, the legal question that arises is: what are the boundaries of privacy? The majority of the judges in *NM and Others* commented on the boundaries of the protection of privacy under the *actio iniuriarum*. They held that the publication of the names of three HIV positive women violated their right to privacy and dignity.³⁴ EHR and electronic private data are often at risk of unlawful access and publication, such as occurred when LinkedIn was hacked in 2012 and private data was published in 2016.³⁵ This leads to the second legal issue of data protection and the legal onus on medical professionals (MPs) to obtain a patient's informed consent when using electronic means to disclose confidential medical information.

Precedent-based legal systems have not kept up with new technologies such as EHR, resulting in a lack of clear legal and ethical guidelines.³⁶ South African statutory provisions such as the Protection of Personal Information Act³⁷ (POPI) and Promotion of Access to Information Act³⁸ (PAIA) and case law on the use of EHR may not be

²⁸ 2007 (5) SA 250 (CC).

²⁹ *NM and Others* supra 131.

³⁰ *NM and Others* supra 151.

³¹ The Constitution of the Republic of South Africa, 1996, section 16(1)(a).

³² *NM and Others* supra.

³³ *NM and Others* supra 45.

³⁴ *NM and Others* supra 89.

³⁵ See: J Pagilery 'Hackers selling 117 million LinkedIn passwords' (2016) available at <http://money.cnn.com/2016/05/19/technology/linkedin-hack/> accessed 16th of August 2016. LinkedIn is a social network that acts as a business platform. Professionals use it extensively to communicate with others in similar business or professional fields

³⁶ DF Sittig & H Singh 'Legal, Ethical, and Financial Dilemmas in Electronic Health Record Adoption and Use' (2011) 127(4) *Pediatrics* e1043. Sittig & Singh discuss numerous other legal dilemmas such as (a) the increased responsibility and accountability placed on the shoulders of MPs; (b) increased liability due to document related issues; (c) the liability that providers face if CDS (clinical decision support) recommendations are not followed; (d) and legal ramifications regarding the usability, quality and reliability of currently available EHR systems.

³⁷ Protection of Personal Information Act 4 of 2013. Hereafter referred to as POPI.

³⁸ Promotion of Access to Information Act 2 of 2000. Hereafter referred to as PAIA.

adequate legal measures.³⁹ In *Mistry v Interim Medical and Dental Council of South Africa*⁴⁰, the Constitutional Court provided some guidelines on data protection.⁴¹ These include the following: whether the data was obtained in an intrusive manner; whether it contained information about the subject's intimate personal life; whether the data was provided for one purpose and used for another; and whether it was disseminated in the press or to the general public from whom the subject could reasonably expect such private information would be withheld.⁴² The POPI⁴³ that was enacted subsequent to this case provides similar guidelines for data protection. Interestingly, section 32 (1)(a) and (b) of the POPI⁴⁴ excludes medical professionals, health institutions and insurance companies from the provisions that prohibit the further processing of personal information. It is submitted that the *lacuna* in relation to the privacy protection of EHR have not been filled. This study examines the gap in statute and the common law in order to assist the formulation of guidelines for informed consent when health records are disclosed using electronic means.

1.3 The broad standards of personality rights protection

Burchell argues that the constitutional protection of personality rights is limited in scope and sets broad standards.⁴⁵ This suggests that personality rights in the electronic era should be more narrowly evaluated in terms of statute and the common law. The National Health Act⁴⁶ (NHA) sets out the following:

- a) Broad standards on confidentiality;
- b) The right of access to records and a duty to maintain such;
- c) The need for consent to disclosure and publication of confidential health records.⁴⁷

The application of these broad statutory standards together with the personality rights of privacy and dignity were examined in the High Court case of *Tshabalala-Msimang*

³⁹ See: HITECH Act of 2009 (US) and based on the writer's observations after reviewing SA statutory law, case law on the subject and practical experience in the use of an EHR system.

⁴⁰ 1998 (4) SA 1127 (CC).

⁴¹ *Mistry supra*.

⁴² *Ibid*.

⁴³ Act 4 of 2013.

⁴⁴ Protection of Personal Information Act 4 of 2013, section 32 (1) (a) & (b).

⁴⁵ Burchell *op cit* 4.

⁴⁶ Act 61 of 2003.

⁴⁷ See: *Tshabalala-Msimang and another v Makhanya and other* 2008 (6) SA 102 (W).

and another *v Makhanya*⁴⁸ that dealt with a paper medical record. This case provided extensive insight into the important constitutional rights of privacy, dignity and freedom of expression and the statutory protection of health records. Chapter three of this study discusses health records and the *Tshabalala-Msimang* case in more detail, while chapter four examines statutory law in relation to informed consent disclosure, access to and protection of health records, and the exceptions that the statute allows. In addition to the NHA⁴⁹, other legislation such as the Consumer Protection Act⁵⁰ (CPA) provides guidance on liability and applicable remedies. This includes situations when health records are unlawfully disclosed without proper informed consent.⁵¹

1.4 The Consumer Protection Act⁵² – strict liability

The CPA introduced no-fault or strict liability, where any person or entity in the supply chain can be held jointly and severally liable for any harm suffered by a consumer (patient).⁵³ It is submitted that harm in the context of this study would be unlawful disclosure of confidential health records by electronic means without proper informed consent. MPs are usually the most easily identifiable person in the supply chain and the easiest for patients to identify and possibly sue.⁵⁴ Neethling et al support the strict imposition of liability based on the argument that electronic data and the collection thereof pose a serious threat to personality rights. They add that the data collector could be held liable without the need to prove intention or negligence.⁵⁵ It is submitted that the fact that there is no need to prove intention or negligence when private health records are unlawfully disclosed when electronic means are used, imposes liability on MPs, purely based on them being part of the healthcare supply chain.

⁴⁸ 2008 (6) SA 102 (W)

⁴⁹ Act 61 of 2003.

⁵⁰ Consumer Protection Act 68 of 2008.

⁵¹ *Tshabalala-Msimang* supra.

⁵² Act 68 of 2008.

⁵³ Consumer Protection Act 68 of 2008, section 61(3),

⁵⁴ K Moodley 'Patients as consumers of health care in South Africa: the ethical and legal implications' (2013) *BMC Medical Ethics* available at

<https://bmcmedethics.biomedcentral.com/articles/10.1186/1472-6939-14-15> accessed 2 April 2017.

⁵⁵ J Neethling JM Potgieter & PJ Visser *Neethling's Law of Personality* 2nd ed (2005) 278.

The CPA has transformed other areas of health law, including the prohibition of unfair, unreasonable or unjust exemption clauses or terms that waive a supplier's liability.⁵⁶ The use of contractual exemption clauses that exclude liability when confidential information is disclosed on an EHR system or via electronic means⁵⁷ is briefly discussed in chapter two. Apart from legal issues with EHR, ethical issues also arise.

1.5 The HPCSA and debate on ethical issues

Professional bodies regulate the ethical conduct of health professionals. The Health Professions Council of South Africa (HPCSA)⁵⁸ has cautioned against the automatic transfer of personal information via electronic means.⁵⁹ However, there are no clear guidelines or precise measures that MPs should adopt.⁶⁰ Cautionary measures are onerous and are often beyond the control of an individual MP. In the US where EHR have been extensively used, ethical issues such as the ownership of records and increased responsibilities on MPs to obtain, inform and prevent a potential breach of a patient's privacy, are the subject of debate.⁶¹ Other ethical issues include the implementation of EHR in developing countries, informed consent, confidentiality, data security and secondary use of data.⁶²

⁵⁶ See: CPA, section 48. See also: DJ McQuoid-Mason 'Hospital exclusion clauses limiting liability for medical malpractice resulting in death or physical or psychological injury: What is the effect of the Consumer Protection Act?' (2012) 5(2) *SAJBL* 65.

⁵⁷ Electronic means: Electronic Communications and Transactions Act 25 of 2002, section 1, defined as part of a 'data message that is generated, sent, received or stored in a voice'.

⁵⁸ The Health Professions Council of South Africa (HPCSA), a statutory body established in terms of the Health Professions Act 56 of 1974. Hereafter referred to as HPCSA.

⁵⁹ HPCSA 'Guidelines for Good Practice in the Health Care Professions' Confidentiality: Protecting and Providing Information, Booklet 5 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%205.pdf accessed 23 July 2017.

⁶⁰ Cautionary measures: (1) Appropriate arrangements for the security of personal information when stored, sent or received by fax, computer, e-mail or other electronic means; (2) If necessary seek appropriate authoritative professional advice on how to keep information secure before connecting to a network and record the fact that such advice has been taken; (3) Ensure that fax machine and computer terminals are in secure areas and if data is sent by fax, they should be satisfied that the data cannot be intercepted or seen by anyone other than the intended recipient; (4) When deciding on what form to transmit personal information, health care practitioners should note that e-mail's may be intercepted.

⁶¹ *Sitting & Singh op cit* e1044.

⁶² MC Were & EM Meslin 'Ethics of implementing electronic health records in developing countries' (2011) *AMIA Annual Symposium Proceedings Archive* 1499.

While the HPCSA recommends general guidelines on ethical issues,⁶³ they are not specifically related to EHR and do not lay down the procedures that should be followed in obtaining consent for the disclosure of confidential information. Apart from the HPCSA guidelines, bioethical principles are used for clinical decisions. These are based on the four principles described by Beauchamp and Childress.⁶⁴ Emanuel et al have also formulated an ethical framework for use in developing countries.⁶⁵ In this study, ethical issues in relation to obtaining informed consent for the disclosure of health records via electronic means are evaluated from two perspectives: The first is the HPCSA guidelines and the second is the bioethical principles using models advocated for use in developing countries such as SA.

1.6 The informed consent controversy

Informed consent has been extensively deliberated on at international and local levels.⁶⁶ Carstens et al conclude that the doctrine of informed consent in medical practice is mired in controversy.⁶⁷ Among other reasons, this is due to it being procedure-specific. The acceptable standard of care for obtaining informed consent was secured in SA jurisprudence in the case of *Castell v de Greef*⁶⁸. *Castell* was cited as a move away from a paternalistic to a more autonomous, patient-centric approach.⁶⁹ Subsequent to *Castell*, the NHA was enacted. Chapter two of this Act⁷⁰ sets out rules on informed consent for medical treatment, as do the HPCSA⁷¹

⁶³ HPCSA 'Guidelines for Good Practice in the Health Care Professions' General ethical guidelines for health care professionals, Booklet 1 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%201.pdf accessed 23 July 2017.

⁶⁴ TL Beauchamp & JF Childress *Principles of Biomedical Ethics* 6th ed (2008).

⁶⁵ See : EJ Emanuel D Wendler J Killen & C Grady 'What makes clinical research in developing countries ethical? The benchmarks of ethical research' (2004) 189(5) *Journal of Infectious Disease* 930-937. See also : Were & Meslin *op cit* 1499.

⁶⁶ See: *Schloendorff v Society of New York Hospitals* 105 N.E. 92 (N.Y. 1914). See also: *Salgo v Leland Stanford Junior University Board of Trustees* 317 P 2d 170 (Cal 1957). See further: *Rogers v Whitaker* [1992] 109 ALR 625. See further: *Stoffberg v Elliot* 1923 CPD 148; *Esterhuizen v Administrator, Transvaal* 1957(3) SA710 (T); *Louwrens v Oldwage* 2006 (2) SA 161 (SCA). See finally: *Castell v de Greef* 1994 (4) SA 408 (C).

⁶⁷ P Carstens & D Pearmain *Foundational Principles of South African Medical Law* (2007) 877.

⁶⁸ 1994 (4) SA 408 (C). *Castell v de Greef* 1994 (4) SA 408 (C), hereafter referred to as *Castell*.

⁶⁹ A Dhali & DJ McQuoid-Mason *Bioethics, Human Rights and Health Law: Principles and Practice* 1 ed (2011) 72.

⁷⁰ National Health Act 61 of 2003, section 6-9.

⁷¹ HPCSA 'Guidelines for Good Practice in the Health Care Professions' Seeking patients informed consent: The ethical considerations, Booklet 4 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%204%20.pdf accessed 23 July 2017.

guidelines. In the democratic era, the question has been raised⁷² as to whether the *Castell* approach is aligned with the Constitution⁷³, the NHA and the National Patients' Rights Charter⁷⁴. Unfortunately, neither the Constitutional Court nor the Supreme Court of Appeal (SCA) has been called on to evaluate the common law position.⁷⁵ Since the enactment of the NHA no judgment has been handed down on informed consent.⁷⁶ Thus, despite technological advancements and the use of EHR via electronic means, there is no legal standard for informed consent for the disclosure of such information.

Carstens et al (2006) question the role and responsibility of the doctor in obtaining informed consent in the electronic era.⁷⁷ They note that South African law should take account of the changing electronic environment that affects the doctor-patient relationship. In other jurisdictions such as the United Kingdom (UK), research and knowledge in this area is more advanced than in SA. Patient expectations, public awareness of EHR systems, informed consent models and the definition of meaningful informed consent were reviewed in the UK.⁷⁸

Riordan et al identify three important factors that guide patients in allowing disclosure of confidential data using electronic means:

- a) '[T]he perceived sensitivity of data;
- b) [The] nature of patient interaction with, and trust, in the data recipient; and
- c) [T]he extent to which individuals feel informed about how their data will be used.'⁷⁹

⁷² R Thomas 'Where to from *Castell v De Greef*? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure' (2007) 124(1) *SALJ* 189.

⁷³ The Constitution of the Republic of South Africa, 1996, section 12 (2) (c). This section provides that: 'Everyone has the right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent.'

⁷⁴ The Department of Health statement on Informed Consent states that 'Everyone has a right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and risks associated therewith and the costs involved.'

⁷⁵ Thomas *op cit* 189.

⁷⁶ R Britz & A le Roux-Kemp 'Voluntary informed consent and good clinical practice for clinical research in South Africa : Ethical and legal perspective' (2012) 102(9) *SAMJ* 746.

⁷⁷ Carstens & Pearmain *op cit* 899.

⁷⁸ F Riordan C Papoutsis JE Reed C Marston D Bell & A Majeed 'Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK' (2015) 84(4) *International Journal of Medical Informatics* 238.

⁷⁹ Riordan et al *op cit* 238.

The study found that different levels of awareness and expectations regarding consent were based on socio-demographic factors and the need for explicit consent.⁸⁰ The current study evaluates the South African legal and ethical standards of care for informed consent when electronic means are used. This is evaluated in the context of some of the unanswered questions raised regarding *Castell*, and in light of the technological era, where electronic means are extensively used in healthcare.⁸¹ The lessons learned from other jurisdictions such as the US and UK which have more extensive legal and ethical guidelines on the use of electronic means in healthcare, are also evaluated.

1.7 Purpose of the study

The purpose of this study is to evaluate the legal and ethical measures MPs take when using EHR and other electronic means, and to assess whether these measures violate a patient's right to privacy and dignity. It also seeks to determine if these measures are legally and ethically adequate to prevent unnecessary litigation and disciplinary action being imposed on MPs.⁸²

1.8 Objectives of the study

The specific objectives of this study are to understand and evaluate the legal and ethical measures, and challenges faced when EHR and electronic means are used in medical practice in SA. Furthermore, it aims to identify inconsistencies or gaps in the law⁸³ and the HPCSA's recommended guidelines.⁸⁴ Based on this evaluation, proposed guidelines and recommendations are presented for implementation and use by MPs in both state and private healthcare services.

1.9 Research questions

To achieve these objectives, the following research questions were posed:

⁸⁰ Riordan et al *op cit* 243.

⁸¹ Thomas *op cit* 189.

⁸² See: WT Oosthuizen & PA Carstens 'Medical malpractice: The extent consequences and causes of the problem' (2015) *THRHR* 78: 270. See also: SS Mangalmurti L Murtagh & MM Mello 'Medical Malpractice Liability in the age of electronic health records' (2010) 363(21) *The New England Journal of Medicine* 2061.

⁸³ Law: Constitution; Statutory law: NHA, Children's Act, amongst other and common law.

⁸⁴ HPCSA Booklet 1 to 15 (2016) available at <http://www.hpcsa.co.za/Conduct/Ethics> accessed 23 July 2017.

- (1) What type of agreement, if any, is required between the MP and patient when health records are disclosed to another MP via electronic means and when using an EHR system?
- 2) What measures should a MP take to ensure that a patient's proper informed consent is obtained to disclose health records via electronic means and on an EHR system?⁸⁵
 - a. The standard of care of how a MP should obtain informed consent and the details that need to be disclosed to the patient.
 - b. How long should the consent last?
 - c. Who should be able to access the health records once informed consent is obtained?
- (3) What steps should a MP take to disclose EHR to another healthcare service provider (including medical aid administrators and insurance companies)?
- (4) What ethical considerations are pertinent to the disclosure of health records via electronic means and on an EHR system?

Medical litigation is on the increase in SA and is expected to escalate during the implementation of EHR systems.⁸⁶ Clarity on the type of agreement and guidelines on informed consent measures and their use in medical practice could help to reduce or prevent unnecessary litigation. *Castell* laid down certain principles for valid informed consent, and evaluated the functionality and legal applicability of these principles when disclosure occurs via the various electronic means used in medical practice. Legislation such as the NHA⁸⁷, POPI⁸⁸ and the Medical Schemes Act⁸⁹ allow third parties such as medical aid administrators and insurance companies to access a patient's health records, provided it is for a legitimate purpose.⁹⁰

⁸⁵ See: FDA 'Draft guidelines on the use of Electronic Health Record Data in clinical investigation' (2016) available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm501068.pdf> accessed on 28 March 2017. See also: The British Psychological Society 'Guidelines on the use of Electronic Health Records' (2011) available at http://www.bps.org.uk/sites/default/files/documents/electronic_health_records_final.pdf accessed 24 August 2016.

⁸⁶ See: Mangalmurti *op cit* 2061. See also: Oosthuizen and Carstens *op cit* 270.

⁸⁷ Act 61 of 2003.

⁸⁸ Act 4 of 2013.

⁸⁹ Act 131 of 1998.

⁹⁰ Legitimate purpose in this context relates to care, rehabilitation, treatment and associated administrative purposes. Also see: U Behrtel 'Anonymous Patient Profiling: Is this ethical and can this data be sold?' (2016) 2(1) *Treatment Tutor* 4.

1.10 Rationale for the study

This study is significant because:

- 1) Since this is an emerging field in SA, clear guidelines that incorporate appropriate legal and ethical measures to obtain informed consent are required.⁹¹
- 2) There is a paucity of academic literature on this subject. The ethics of the current practice of obtaining informed consent for the disclosure of confidential information on an EHR system have been called into question due to a lack of information and consensus on the risks, benefits and costs.⁹²
- 3) There is also limited legal and ethical knowledge on EHR from other jurisdictions.⁹³ While there are a few reported cases in the US, there are none in SA.
- 4) The increase in cybercrime and hacking of confidential personal information call for additional security features to be put in place and for the risks to be explained to patients as part of the informed consent process.⁹⁴

1.11 Research design and methodology

This study involved an evaluative and critical analysis of the legal and ethical measures used when EHR via electronic means are used in medical practice in SA. A qualitative and descriptive approach was adopted. Data was sourced from books, journals, conference papers, policy documents, guidelines formulated by professional bodies, bills, draft regulations, local and international newspapers, the Constitution⁹⁵, South African and foreign statutory law and case law, articles from the internet and local and foreign law reports. The methodology included a desktop search of the

⁹¹ See: MPS 'Medical Records in South Africa: An MPS guide' (2014) available at <http://www.medicalprotection.org/southafrica/advice-booklets/medical-records-in-south-africa-an-mps-guide> accessed on 25 September 2016. Medical Protection Society (MPS, referred to hereafter), is an insurer of medical professionals. This document provides some basic information on confidentiality and the duty to obtain informed consent when using EHR. However, these guidelines lack details on measures that should be used in this process.

⁹² A Gary Y Vawda & C Jack 'Health policy and legislation' (2013) *South African Health Review* available at <http://www.hst.org.za/publications/south-african-health-review-2012/13> accessed 24 September 2016.

⁹³ See: Were & Meslin *op cit* 1499. See also: Mangalmurti et al *op cit* 2061. See further: Singing & Singh *op cit* e1044.

⁹⁴ See: H Kelly 'What to do if you Yahoo account was hacked' (2016) available at <http://money.cnn.com/2016/09/22/technology/yahoo-hack-password-tips/> accessed 24 September 2016. See also: Pagilery *op cit*.

⁹⁵ The Constitution of the Republic of South Africa, 1996.

following databases: LexisNexis, Juta, Sabinet, Heinonline, Ebscohost, West Law, SAFLII, and Google Scholar, amongst others.

This research design and methodology enabled an evaluation of the measures used to obtain consent to disclose health records via electronic means and to achieve the objectives discussed above.

1.12 Structure of the dissertation

Chapter one introduces the issue of the right to privacy and dignity and briefly discusses the constitutional right to privacy and dignity. It outlines the research objectives and questions and the rationale for the study.

Chapter two discusses the doctor-patient relationship and whether it has changed in the electronic era. It briefly discusses exemption clauses and their use to exclude liability when electronic means and EHR are used. This is followed by a discussion on the concept of confidentiality, and the doctrine of informed consent and whether this doctrine is relevant when EHR and electronic means are used to disclose private and confidential medical information.

Chapter three focuses on health records, their history, composition, ownership and the difference between electronic and paper-based health records. South African common law on health records is critically discussed. The security of EHR and hacking of electronic health record systems is also discussed.

Chapter four discusses the constitutional rights to dignity, privacy and freedom of expression and the statutory law in relation to EHR. Statutory measures on informed consent, privacy, access to health records, and protection of health records seem to be adequate from a doctor-patient-EHR perspective. Security, hacking and authentication in cyberspace are discussed in relation to models used in the financial sector. The HPCSA guidelines on record keeping, telemedicine and electronic records are

critically evaluated. Finally, ethical models, liability and Medical Protection Society (MPS) guidelines are evaluated in relation to the use of EHR.⁹⁶

Chapter five presents a brief comparative analysis of EHR in the US and UK.

Chapter six presents the conclusions drawn from the evaluation and critical analysis and makes recommendations.

⁹⁶ MPS 'Medical Records in South Africa: An MPS Guide' available at <http://www.medicalprotection.org/southafrica/advice-booklets/medical-records-in-south-africa-an-mps-guide> accessed 14 April 2017. MPS is a large medical practitioner insurer that has provided some basic guidelines (non-binding) for MPs to use or refer to when using an electronic health records.

CHAPTER TWO

‘What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.’ Hippocratic Oath, written in the 4th century BC.⁹⁷

2.1 Introduction

The medical practitioner (MP)-patient relationship is sacred.⁹⁸ No legal formalities are required for the birth, continued existence and termination of such a relationship.⁹⁹ This legal relationship varies globally, with different rules applied in different jurisdictions.¹⁰⁰ Generally in medical practice, *consensus ad idem* (meeting of the minds)¹⁰¹ results in either a tacit (implied), oral or written agreement.¹⁰² This culminates in a legally binding MP-patient contract. However in circumstances where a duty of care arises and no MP-patient contract exists, a breach of this legal duty can give rise to a delictual claim. A delict occurs when the law imposes a duty of care and is not adhered to as opposed to a contract that is voluntarily entered into and has legal consequences when breached.¹⁰³

The precise legal meaning of *consensus ad idem* is controversial, and it is regarded as a philosophical rather than a legal concept.¹⁰⁴ In *SAR & H v National Bank of SA Ltd*¹⁰⁵, Wessels JA offered some clarity and guidance on the interpretation of this concept. He stated that the law concerns itself with the external manifestations of a contracting party’s mind and not its subjective working.¹⁰⁶ This raises the question of whether an implied, written or an oral contract is required when health records are

⁹⁷ Hippocratic Oath ‘Classical Version’ available at <http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html> accessed 3 July 2016.

⁹⁸ Ibid.

⁹⁹ See: SA Strauss *Doctor, Patient and the Law* 3 ed (1992) 12. See also RH Christie & GB Bradfield ‘Christie’s: *The law of contract in South Africa*’ 6th ed (2011) 8.

¹⁰⁰ See: V Blake ‘When is a Patient-Physician Relationship Established’ (2012) 14(5) *Virtual Mentor* 403-404. See also: *Hurley v Eddingfield* 59 NE 1058 (Ind 1901); *Ricks v Budge* 64 P2d 208 (Utah 1937); *Childs v Weis* 440 SW2d 104 (Ct Civ App Tx 1969); *Mead v Adler* 220 P3d 118 (Or 2009).

¹⁰¹ *Consensus ad idem* in South African medical practice would translate into the MPs and patient’s minds meeting on the offer to treat by the patient and the MP accepting the offer. This generally occurs once the patient enters the MP’s rooms and the MP starts a consult with the patient.

¹⁰² Christie & Bradfield *op cit* 24.

¹⁰³ Neethling Potgieter & Knobel *op cit* 6. It has been argued that there is no essential difference between these legal phenomena (a delict and breach of contract) except that fault is not a requirement for a claim for damages based upon a breach of contract.

¹⁰⁴ Christie & Bradfield *op cit* 8.

¹⁰⁵ 1924 AD 704.

¹⁰⁶ See: *SAR & H v National Bank of SA Ltd* 1924 AD 704 715.

disclosed electronically. An evaluation of the common law of contract, including contractual clauses, and the legal concept of confidentiality, and doctrine of informed consent in healthcare, provide guidance in answering this question.

2.2 Healthcare contracts and contractual clauses

Pacta sunt servanda, a common law contractual term that translates to agreement must be kept, applies equally to MP-patient agreements.¹⁰⁷ This binds an MP and the patient to their contractual agreement. At common law generally included contracts that were perceived as being unfair.¹⁰⁸ Prior to the constitutional era, South African courts did not generally intervene in a contractual relationship if it merely offended one of the party's personal sense of fairness and equity.¹⁰⁹ In the current constitutional dispensation, the role of good faith, reasonableness and fairness have not been considered as reasons for the court to intervene in a contractual relationship.¹¹⁰ Generally, a written contract is substantive evidence of the agreed terms. A written contract might contain exemption clauses that exclude liability on the part of one or more contracting parties. Exemption clauses that exclude liability for a negligent act remain controversial in SA.¹¹¹

The SCA had the opportunity to decide on the application of an exemption clause in a healthcare contract in the *Afrox Health Care Ltd v Strydom*¹¹² case. The facts of the case are as follows: Strydom (the patient) was admitted to one of the Afrox group of private hospitals for an operation. He signed a standard contract form that contained an exemption clause that absolved the hospital from all form of liability for negligent acts by nursing staff. Strydom developed complications following the operation that were attributed to the negligence of nursing staff. He sued Afrox Health Care for damages arising from these complications. Afrox relied on the exemption clause and

¹⁰⁷ *Pacta sunt servanda*: Latin expression, stating that courts will enforce contracts and the will of the contracting parties.

¹⁰⁸ See: *Afrox Health Care Ltd v Strydom* 2002 (6) SA 21 (SCA).

¹⁰⁹ FDJ Brand 'The Role of Good Faith, Equity and Fairness in the South African Law of Contract: The Influence of the Common Law and the Constitution' (2009) *South African Law Journal* 126(1) 71-90.

¹¹⁰ See: *Brisley v Drotsky* 2002 (4) SA 1 (SCA). Hereafter referred to as *Brisley v Drotsky*.

¹¹¹ See: T Naude and G Lubbe 'Exemption Clause – A Rethink Occasioned by the *Afrox Healthcare BPK v Strydom*' (2005) *The South African Law Journal* 5(1) 441-463. See also: DJ McQuoid-Mason 'Hospital exclusion clauses limiting liability for medical malpractice resulting in death or physical or psychological injury: What is the effect of the Consumer Protection Act?' (2012) *SAJBL* 5(2) 65-68.

¹¹² *Afrox Health Care BPK v Strydom* 2002 (6) SA 21 (SCA). Hereafter referred to as *Afrox Health Care* case.

Strydom argued in his defense *inter alia* that this clause was against public policy because it was unreasonable, unfair and in conflict with the principle of good faith. The court confirmed an earlier SCA decision in *Brisley v Drotzky* that good faith, reasonableness and fairness are substantial reasons for interference by the courts in contractual relationships. However the SCA decided that the exemption clause was valid.¹¹³ Thus application of good faith and equity were held not to be substantive rule in SA. This was confirmed in a further SCA judgment in *South African Forestry Ltd v York Timbers Ltd*¹¹⁴. Therefore, based on these SCA decisions, at common law an exemption clause that is not in good faith, unreasonable and unfair may be valid in South African law.¹¹⁵ However the introduction of the CPA¹¹⁶ has changed this.¹¹⁷

The *Afrox Health Care* case has been criticized for placing a healthcare contract in the broader category of a commercial contract.¹¹⁸ This is detrimental to patients. Exemption clauses such as these undermine the reasons why patients seek healthcare services, and the principle of reciprocity of healthcare contracts.¹¹⁹ The CPA has introduced provisions that raise questions on the validity and application of exemption clauses in healthcare contracts.¹²⁰

Terms that are presumed to be unjust, unfair and unreasonable constitute a breach of the CPA.¹²¹ These include clauses that are aimed at limiting or excluding certain consumer rights. The provisions of the CPA suggest that courts may no longer validly apply the *Afrox Health Care* decision. However in SA, exemption clauses' are still widely used in healthcare contracts.¹²² Academics argue that exemption clauses that are unjust, unfair and unreasonable have no valid place in healthcare contracts and

¹¹³ *Afrox Health Care* supra 31-32.

¹¹⁴ 2005 (3) SA 323 (SCA).

¹¹⁵ See: *Afrox Health Care* supra. See: *Brisley v Drotzky* supra. *South African Forestry Ltd* supra.

¹¹⁶ Act 68 Of 2008.

¹¹⁷ See: Discussion on the CPA below.

¹¹⁸ Naude & Lubbe *op cit* 441-463.

¹¹⁹ *Ibid*.

¹²⁰ See: K Rowe & K Moodley 'Patients are consumers in healthcare in South Africa: the ethical and legal implications' (2013) 14(15) *BMC Medical Ethics* 1-9. See also: MS Pepper and MN Slabbert 'Is South Africa on the verge of a medical malpractice litigation storm' (2011) 4(1) *SAJBL* 32.

¹²¹ See: CPA, section 52(3).

¹²² The writer quotes from his own personal experience as a private medical practitioner and as an advocate. The private healthcare hospital sector still uses exemption clauses that limit liability in health care contracts. This includes the use of exemption clauses by medical aid administrators that exclude liability for negligent disclosure when EHR are used.

may in future be declared unconstitutional and invalid.¹²³ The writer supports the invalidating of such clauses in healthcare contracts.¹²⁴ It is submitted that written contracts that do not use unjust, unfair and unreasonable terms should be used in healthcare contracts generally and those that are used for EHR and disclosure of health records via electronic means. Confidentiality and informed consent are important issues in the MP-patient-electronic era.

2.3 Confidentiality in medical practice

Confidentiality forms the lifeblood of medical practice; the Hippocratic Oath is at the epicenter, guaranteeing that confidentiality is ethically maintained. The NHA¹²⁵ codifies confidentiality concerning a patient's health status, treatment or stay in a healthcare establishment.¹²⁶ However, confidentiality in medical practice is not absolute.¹²⁷ The NHA provides for exceptions to the statutory rule on confidentiality.¹²⁸ Written informed consent, a court order and public interests are some of the exceptions provided for in the NHA. Ethical rules, such as those provided by the HPCSA allow for further exceptions for a breach of confidentiality in the patient-MP relationship.¹²⁹ The disclosure of a patient's HIV status can be disclosed to his or her sexual contacts in certain circumstances.¹³⁰

In healthcare, confidentiality safeguards private and public healthcare initiatives. In the *X v Y*¹³¹ case, Rose J stated the following in support of the preservation of confidentiality in medical practice:

‘In the long run, preservation of confidentiality is the only way of securing public health; otherwise doctors will be discredited as a source of education, for future individual patients “will not come forward if doctors will squeal on them.”

¹²³ See: McQuoid-Mason (2012: *SAJBL*) *op cit* 67.

¹²⁴ Submission is based on provisions, Section 52(3) CPA ; Section 48 & 49 CPA ; Section 52 (4) CPA.

¹²⁵ National Health Act 61 of 2003. Hereafter referred to as NHA

¹²⁶ See: NHA, section 14(1).

¹²⁷ See: *Parkes v Parkes* 1916 CPD 702; *Botha v Botha* 1972 (2) SA 559 (N):- A court ordered disclosure of confidential information. See also: An Act of parliament requires disclosure of confidential. See further: *Tarasoff v Regents of the University of California* (1976) Cal SCT, 17 Cal Rep 3rd series 425: threat to an endangered third party.

¹²⁸ See: NHA, section 14(1) read with section 14(2). Allows disclosure if a court order or any other law allows disclosure and when public health is threatened by non-disclosure.

¹²⁹ HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Ethical guidelines for good practise with regards to HIV, Booklet 6 (2016) available at accessed 23 July 2017.

¹³⁰ *Ibid.*

¹³¹ *X v Y* 1988 ALL ER 648 (QBD).

Consequently, confidentiality is vital to secure public as well as private health, for unless those infected come they cannot be counseled and self-treatment does not provide the best care ...¹³²

The electronic era has been implicated in meddling in the MP-patient confidential relationship.¹³³

Internationally there is debate on the evolution of confidentiality aspects of electronic communication and the redefinition of the patient-MP relationship.¹³⁴ The words of Rose J need to be considered with the objective of maintaining, securing and preserving health confidentiality aspects when EHR and electronic means are used. It is asserted that SA jurisprudence on privacy and confidentiality in the electronic era is in its infancy. Securing and preserving confidentiality thus remains a challenge. Privacy and security have been cited as major patient concerns with the use of EHR in foreign jurisdictions.¹³⁵

Despite the significant benefits of national EHR programmes, SA has lagged behind developed countries.¹³⁶ Thus, it is asserted that legal and ethical measures need to be formulated to overcome confidentiality challenges when electronic means are used. In the South African legal context, confidentiality will be assessed in terms of the common law. Chapter four will focus on the issue of overcoming the security challenge of EHR.

*Jansen Van Vuuren v Kruger*¹³⁷ is the authoritative common law case on confidentiality and disclosure. In this case, the breach of confidentiality involved unlawful disclosure of the results of a patient's human immunodeficiency virus (HIV) test. Unlawful disclosure of a positive result can have severe and drastic consequences for the affected party (patient). Stigma against HIV positive people is highly prevalent

¹³² *X v Y* supra 653 a-b.

¹³³ Carstens & Pearmain *op cit* 899.

¹³⁴ See: Wright *op cit* 1.

¹³⁵ NP Terry & LP Francis 'Ensuring the privacy and confidentiality of electronic health records' (2007) *University of Illinois Law Review* 861(2) 681-736.

¹³⁶ *Ibid.*

¹³⁷ *Jansen Van Vuuren v Kruger* 1993 (4) SA 842 (A). Hereafter referred to as *Jansen Van Vuuren v Kruger*

in South African society. In *Hoffmann v South African Airways*¹³⁸ the court ruled on unfair and discriminatory labour practices based on the applicant's HIV status. Generally, a person's HIV status is highly sensitive and needs to be protected.¹³⁹ *Jansen Van Vuuren v Kruger* has shown that the unlawful disclosure of an HIV test result has the potential to spread rapidly in communities. *Hoffmann v South African Airways* demonstrated that discrimination based on a person's HIV status exists; impairs their dignity and can affect their employment status. It is submitted that in this era of electronic technology, the potential for abuse of such technology enables the exponential and rapid spread of gossip, such as about a person's HIV status.¹⁴⁰ If patients perceive that an EHR system is not adequately protected, they might resort to false or non-disclosure of such information or develop a culture of mistrust in the EHR system.¹⁴¹

Circumstances may exist where unauthorized disclosure of health records may be deemed not to be severe. Such disclosure will have little or no impact on the patient's right to dignity and privacy. In *Hague v Williams* (Supreme Court of New Jersey) such disclosure occurred when a child's health records were disclosed to an insurance company.¹⁴² It is asserted that certain health records require added security and protection. This would warrant risk stratification of confidential medical data.¹⁴³ The NHA provides for specific legal rules when disclosing confidential health records.¹⁴⁴

¹³⁸ *Hoffmann v South African Airways* 2000 (11) BCLR 1211 (CC); 2001 (1) SA (CC). Hereafter referred to as *Hoffmann v South African Airways*.

¹³⁹ See: *Jansen Van Vuuren v Kruger* 1993 (4) SA 842 (A). *Hoffmann v South African Airways* 2000 (11) BCLR 1211 (CC); 2001 (1) SA (CC). *N v Minister of Defence* (2000) ILJ 999 (Labour Court of Namibia).

¹⁴⁰ See: *Dutch Reformed Church v Rayan Sooknunan* 2012 (6) SA 201 (GSJ). See also: *Willis J in Heroldt v Wills* 2013 (2) SA 530 (GSJ). See further: *Isparta v Richter* 2013 (6) SA 4529 (GP). These cases involved defamation claims and the publication of defamatory information on Facebook, a social media electronic website.

¹⁴¹ *Terry & Francis op cit* 698.

¹⁴² *Hague v Williams* 1962 (181) Atlantic Reporter 2d 345 (NJ) at 349. In this case it was held that 'knowledge and the extra-curial disclosure of a child's pathological heart condition was not of such a confidential nature that it prevented the physician from disclosing the health record to an insurer to whom the parents have applied for life insurance on the child.'

¹⁴³ See: Chapter four for further discussion on legislation and protection measures.

It is submitted that risk stratification involves the following: the type of information; the potential nature of harm to be suffered; the extent of the disclosure; the scope of the disclosure; the time frame of the disclosure; and consideration of applicable legislation and the HPCSA's guidelines.

¹⁴⁴ These specific and other relevant sections of the NHA as well as other applicable legislation are discussed in chapter four.

The HPCSA also offers guidelines on confidentiality that will be discussed later.¹⁴⁵ The NHA and the common law provide that a patient's informed consent is an exception to these rules. Thus, a doctrine of informed consent has been established in medical practice.

2.4 The doctrine of informed consent in medical practice

Informed consent has been documented in ancient civilizations¹⁴⁶, dating back to the 3rd century B.C.¹⁴⁷ In those days, an MP (doctor) was sentenced to death for not obtaining a patient's permission prior to performing major surgery.¹⁴⁸ Evolving from this era, there is documented evidence of informed consent in a contractual form in Spain in 1889.¹⁴⁹ This was recorded in relation to experiments on the causes of Yellow Fever infection.¹⁵⁰ However, the term "informed consent" was only given legal standing in 1914 in the US case of *Schloendorff v Society of New York Hospitals*¹⁵¹, which involved the removal of a tumor under general anesthetic.¹⁵² The doctrine of informed consent is critically evaluated to determine whether it is applicable when EHR and electronic means are used in medical practice.

The doctrine of informed consent was formulated and given its original form in the case of *Salgo v Leland Stanford Junior University Board of Trustees*¹⁵³ (US) in 1957. It spread to various global jurisdictions, including Australia (1992), in the *Rogers v Whitaker*¹⁵⁴ case. SA first introduced the doctrine of informed consent in the case of

¹⁴⁵ HPCSA 'Guidelines for Good Practice in the Health Care Professions' Confidentiality: Protecting and Providing Information, Booklet 5 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%205.pdf accessed 23 July 2017.

¹⁴⁶ These included Greek, Roman and Indian civilization, amongst others.

¹⁴⁷ See: NK Kumar 'Informed consent: Past and present' (2013) 4(1) *Perspective in clinical Research* 21-25.

¹⁴⁸ Ibid.

¹⁴⁹ Kumar *op cit* 23.

¹⁵⁰ Ibid.

¹⁵¹ *Schloendorff v Society of New York Hospitals* 105 N.E. 92 (N.Y. 1914). Hereafter referred to as *Schloendorff v Society of New York Hospitals* case.

¹⁵² *Schloendorff v Society of New York Hospitals*. In this case consent for an abdominal examination did not constitute 'informed consent' when the patient (Schloendorff) had a tumor removed under general anesthetic, which was not part of the consented procedure. However, there might be circumstances where an acceptable deviation from the consented procedure might be warranted and can be disclosed to a patient thereafter.

¹⁵³ *Salgo v Leland Stanford Junior University Board of Trustees* 317 P 2d 170 (Cal 1957).

¹⁵⁴ *Rogers v Whitaker* [1992] 109 ALR 625.

*Richter and another v Estate Hammann*¹⁵⁵ in 1976 and its application was secured in the *Castell v de Greef*¹⁵⁶ case in 1994.¹⁵⁷ *Castell* incorporated the principle of the test on informed consent from the *Rogers* case (*Rogers* test), that of the ‘reasonable patient test’.¹⁵⁸ *Castell* has seen a distinct move away from the ‘reasonable doctor test’¹⁵⁹ to the ‘reasonable patient test’. This gave effect to the meaning to informed consent from a patient’s perspective, the ‘*Rogers* test’ established in the Australian case (1992).¹⁶⁰ These two tests were evaluated to determine a ‘material risk’ and will be further discussed later.

The *Castell* case (pre-constitutional) has become guiding law on informed consent and disclosure in SA, due to the principle of a ‘reasonable patient test’, established therein. This patient-centred (subjective) test was further affirmed in *Broude v McIntosh*¹⁶¹ and *McDonald v Wroe*¹⁶². However, in the case of *Louwrens v Oldwage*¹⁶³ the court a quo accepted the subjective patient-centred test for disclosure but the Court of Appeal used the ‘professional standard test’ (medical judgment) for disclosure from *Richter and another v Estate Hammann*^{164,165}. In the absence of any further SCA or Constitutional Court ruling on the doctrine, the *Castell* test remains the principle standard that is applied by South African courts.

Post-constitutionally, SA has enacted other legislation such as the NHA¹⁶⁶, the Mental Health Care Act¹⁶⁷, the CPA¹⁶⁸, the PAIA¹⁶⁹, and more recently the POPI¹⁷⁰ as well as various other statutory laws that relate to healthcare, confidentiality and informed consent, that impact on the MP-patient relationship. *Castell* formulated and used

¹⁵⁵ *Richter and another v Estate Hammann* 1967 (3) SA 226 (C).

¹⁵⁶ *Castell v de Greef* 1994 (4) SA 408 (C). Hereafter referred to as *Castell*.

¹⁵⁷ Britz & le Roux-Kemp *op cit* 746.

¹⁵⁸ Thomas *op cit* 196.

¹⁵⁹ See: *Van Wyk v Lewis* 1924 AD 438. A standard of care that is required of a health practitioner in that particular field. A greater skill is required of a specialist in his field than a general practitioner.

¹⁶⁰ See: *Rogers v Whitaker* supra.

¹⁶¹ 1998 (3) SA 60 (SCA).

¹⁶² 2006 (3) All SA 565 (C).

¹⁶³ 2006 (2) SA 161 (SCA).

¹⁶⁴ 1976 (3) SA 226 (C).

¹⁶⁵ Britz & le Roux-Kemp *op cit* 747.

¹⁶⁶ Act 61 of 2003.

¹⁶⁷ Act 17 of 2002.

¹⁶⁸ Act 68 of 2008.

¹⁶⁹ Act 2 of 2000.

¹⁷⁰ Act 4 of 2013.

certain important principles in determining whether proper informed consent has been solicited from the patient.

In *Castell*, the court considered whether non-disclosure of all the complications by the surgeon was ‘non-material’. Failure to provide an exact percentage of the degree of risk of complications was deemed to be ‘non-material’. *Castell v De Greef* thus helped to define the principles that can be used to determine whether informed consent was properly solicited from a patient. The following principle on informed consent emanated from the case:¹⁷¹

- 1) ‘Knowledge of the nature and extent of harm or risk;
- 2) Appreciate and understanding of the nature of harm or risk;
- 3) Consent to the harm or assume the risk;
- 4) Consent extends to entire transaction and must be comprehensive, including consequences thereof.’¹⁷²

The principles derived from *Castell* have found application in various branches of medical practice, including clinical and research applications. Importantly, the principles of informed consent were applied in *C v Minister of Correctional Services*,¹⁷³ where an HIV test conducted on a prisoner without proper informed consent in the form of pre-test counseling was held to be an invasion of privacy.

Current South African academic literature on the clinical use and application of EHR systems is scarce. Despite various academic debates on legal and ethical issues such as ownership (property rights), control, security and privacy issues in the use of such systems, little practical application or guidance has been forthcoming or confirmed by application in South African case law. Thus, surveys and the academic literature from other jurisdictions are used to critically evaluate EHR consent models.

Surveys on the use of EHR consent models and patients’ attitudes towards the use of such models in the UK indicate that:

¹⁷¹ *Castell v de Greef* 1994 (4) SA 408 (C).

¹⁷² See: *Castell* supra. See also: D McQuoid-Mason ‘What constitutes medical negligence?: A current perspective on negligence versus malpractice’ (2010) 7(4) *SAHeart* 249.

¹⁷³ See: *C v Minister of Correctional Services* 1996 (4) SA 292 (T). The Department had a procedure and guidelines in place for the HIV testing of prisoners and failed to follow its own procedure in this case.

- 1) '[The] vast majority (91%) expected that an *opt-in* form of explicit consent be obtained before identifiable health data could be shared for health policy, research and health provisions;
- 2) Half (49 %) of the study population expected that de-identifiable [data] could be used;
- 3) Awareness of EHR was low and those that were aware were more willing to share de-identifiable [data] without their consent; and
- 4) Socio-demographics played [a role] in awareness levels and consent expectations.'¹⁷⁴

Similar studies in Canada produced similar results.¹⁷⁵

It is submitted that the South African socio-demographic medical landscape is complex and has been complicated by the following in the state healthcare system:

- 1) Apartheid with its resultant pluralistic healthcare system resulted in the majority of patients accessing the under-resourced state system.¹⁷⁶
- 2) Low literacy levels, the fact that there are eleven official languages and communication barriers with MPs that service predominately rural patients further complicate and hinder attempts to obtain meaningful proper informed consent.¹⁷⁷

It is submitted that patients that utilise state services often do not provide meaningful voluntary informed consent due to low literacy levels and the lack of resources that are required in sometimes complex clinical situations. As noted earlier, EHR usage is confined to one state hospital.

The private healthcare system in SA treats a smaller percentage of the population and is better resourced.¹⁷⁸ Medical aid schemes predominantly fund this sector through premiums collected from patients. The use of an EHR by a medical aid administrator is limited to one administrator.¹⁷⁹ The issue with informed consent when EHR is used

¹⁷⁴ F Riordan et al *op cit* 237-247.

¹⁷⁵ Riordan et al *op cit* 244.

¹⁷⁶ BM Mayosi and SR. Benatar 'Health and Health Care in South Africa — 20 Years after Mandela' (2014) 371(14) *New England Journal of Medicine* 1344-1353.

¹⁷⁷ Ibid.

¹⁷⁸ Econex 'The South African Private Healthcare Sector: Role and Contribution to the Economy' (2013) available at <http://www.mm3admin.co.za/documents/docmanager/f447b607-3c8f-4eb7-8da4-11bca747079f/00060290.pdf> accessed 11 June 2017.

¹⁷⁹ See: Discovery 'HealthID: The technology that puts your patients' health records in your hands' (2016) available at <https://www.discovery.co.za/portal/individual/health-id> accessed 5 September 2016.

in this sector is voluntariness or the lack thereof.¹⁸⁰ In such circumstances, a patient often signs a consent form for disclosure of identifiable data on an EHR system for fear of not receiving the service if consent is denied.¹⁸¹ Voluntariness is one of the four elements of informed consent; the others are disclosure, understanding and decision-making capacity.¹⁸² It is submitted that all these elements must be present when a patient provides ‘meaningful consent’ for participation in an EHR system. When patient consents under duress¹⁸³, this would not be voluntary informed consent and can be declared legally invalid. The ethical equivalent of voluntariness is autonomy.¹⁸⁴ It is equally applicable when informed consent is obtained for the disclosure of identifiable and non-identifiable data on an EHR system.¹⁸⁵

2.5 Ethics and the HPCSA guidelines on informed consent

The development of ethics in the medical sector and the pivotal role of informed consent have a controversial past that is tainted by gross human rights violations.¹⁸⁶ However important codes, studies and reports spurred the development of modern day medical ethics. These are as follows:

- 1) The Nuremberg Code¹⁸⁷ (1947);
- 2) The Tuskegee Syphilis Study of the Public Health Service Department of the US government¹⁸⁸ (1932 to 1972); and
- 3) The Belmont Report¹⁸⁹ by the US government (1979). The commission was directed to consider:
 - (i) ‘[T]he boundaries between biomedical and behavioral research and the accepted and routine practice of medicine;

¹⁸⁰ Submissions are based on the writer’s personal experiences in the health care sector since 1995 as a MP, and his experience in healthcare management and as a legal advisor to the medical sector.

¹⁸¹ Ibid.

¹⁸² A Cahana & SA Hurst ‘Voluntary informed consent in research and clinical care: an update’ (2008) 8(6) *Pain Practice* 446-451.

¹⁸³ Duress in this instance would be signing a consent form ‘out of fear’ of treatment being denied or being prejudiced in any manner.

¹⁸⁴ See: TL Beauchamp & JF Childress *Principles of biomedical ethics* (1994) 4. See also: Britz & le Roux-Kemp *op cit* 746-748.

¹⁸⁵ See: Cahana & Hurst *op cit* 446-451.

¹⁸⁶ See: Nuremberg Code ‘Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law’ (1949) available at <https://history.nih.gov/research/downloads/nuremberg.pdf> accessed 11 June 2017.

¹⁸⁷ Ibid.

¹⁸⁸ See: US Public Health Service ‘Tuskegee study of untreated syphilis in the negro male’ available at <https://www.cdc.gov/tuskegee/timeline.htm> accessed 1 July 2017.

¹⁸⁹ See: U.S Department of Health and Human Services. Belmont Report 1979 available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> accessed 29 March 2017.

- (ii) [T]he role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects;
- (iii) [A]ppropriate guidelines for the selection of human subjects for participation in such research; and
- (iv) [T]he nature and definition of informed consent in various research settings.’

This resulted in the formulation of the ethical principles of respect for persons, beneficence and justice in conducting research.¹⁹⁰ Although similar, the refinement and newly defined principles of autonomy, non-maleficence, beneficence and justice gave birth to biomedical ethics (bioethics) or clinical ethics.¹⁹¹ These ethical principles equally apply to consent for the use of EHR and the use of electronic means in medical practice. Autonomy is the apex of bioethics and has been brought to the fore by these codes, studies and reports.¹⁹²

It has been argued that autonomy has only contributory value in clinical medical practice.¹⁹³ Bioethicists have also maintained that despite the fact that others may be in a better position to make an informed decision on a patient’s well-being, patients must be given the opportunity to make their own decision.¹⁹⁴ In its commonest form in daily clinical medical practice, autonomy allows a patient to make decisions, even if they are bad and do not promote their wellbeing.¹⁹⁵ Only in a few limited circumstances can a patient’s autonomy be limited.¹⁹⁶ These include situations where a patients requests a doctor to conduct unethical or illegal treatment or procedures and circumstances that justify informing the patient at a later stage of the reasons for

¹⁹⁰ Ibid.

¹⁹¹ Beauchamp & Childress *op cit* 4.

¹⁹² J Moreno ‘The Triumph of Autonomy in Bioethics and Commercialism in American Healthcare.’ (2007) 16(4) *Cambridge Quarterly of Healthcare Ethics* 415-419.

¹⁹³ See: J Varelus ‘The value of autonomy in medical ethics’ (2006) 9(3) *Medicine Health Care Philosophy* 377–388.

¹⁹⁴ See: JD Glover *Causing Death and Saving Lives* (1977) 80. See also: R Gillon ‘Ethics Needs Principles – Four Can Encompass the Rest – and Respect for Autonomy Should be First Among Equals’ (2003) 29(5) *Journal of Medical Ethics* 310. See further: J Harris ‘Consent and End of Life Decisions’ (2003) 29(1) *Journal of Medical Ethics* 11.

¹⁹⁵ See: *Hay v B* 2003 (3) SA 492 (W). The most common and widely cited example when a Jehovah’s Witness in need of medical treatment such as a blood transfusion declines such treatment based on their religious faith.

¹⁹⁶ DJ McQuoid-Mason ‘Michael Jackson and the limits of patient autonomy’ (2012) 5(1) *SAJBL* 11-14.

adopting a paternalistic approach.¹⁹⁷ The intrinsic value and rationale for individual willful decision-making capacity in clinical medical ethics is a kind of higher law that professional bodies such as the HPCSA use in decision-making.

The HPCSA guidelines on informed consent provide a standard for the evaluation of misconduct complaints against an MP.¹⁹⁸ Dialogue is recommended for effective communication between an MP and a patient. An ethical obligation is placed on the MP to determine what appropriate information a patient needs to know. Information relating to the proposed treatment, the risks, costs and the consequences thereof are important aspects of informed consent.¹⁹⁹ It is asserted that such information should include whether information/data is to be disclosed to a third party via electronic means or on an EHR system. Unfortunately the HPCSA lacks specific guidelines or measures on this issue.

2.6 Conclusion

Medical practice contractual relationships go beyond the relationship between a single MP and a patient. They extend to other healthcare service providers including medical aid administrators, insurance companies and other medical practitioners. A complex array of contractual clauses, including exemption clauses may exist within these contracts. Exemption clauses may exclude or limit liability from delictual action arising from the actions of staff members or directly from contracting parties.²⁰⁰ The legitimacy of such clauses remains debatable amongst academics. Despite the complexities that multiple contacts might pose in medical practice, confidentiality remains the lifeblood of daily practice and is protected by the Constitution²⁰¹, common law, statutory law, and HPCSA rules.²⁰² Informed consent, whether written or oral, is an exception to these legal and ethical rules. Patients must be provided with

¹⁹⁷ These circumstances could include an emergency situation where the patient requires urgent medical intervention or may be in a comatose state, with no nominated person being available to make a more informed decision.

¹⁹⁸ HPCSA 'Guidelines for Good Practice in the Health Care Professions' Seeking patients Informed Consent: The Ethical Considerations, Booklet 4 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%204%20.pdf accessed 23 July 2017.

¹⁹⁹ Ibid.

²⁰⁰ See: *Afrox Health Care* supra.

²⁰¹ The Constitution of the Republic of South Africa, 1996.

²⁰² See: *Jansen Van Vuuren v Kruger* supra. See also: the National Health Act 61 of 2003; the Mental Health Care Act 17 of 2002; the Children's Act 38 of 2005 and the Choice on Termination of Pregnancy Act 92 of 1996. See further: HPCSA Booklet 5 (2016).

information to make an informed decision on whether or not to use an EHR system. The doctrine of informed consent and the principles that *Castell* introduced to South African law, apply to the use of EHR or electronic means. Evaluation of paper-based health records and EHR will help to develop recommended measures for the use of EHR and electronic means. Chapter three discusses health records, including ownership, the difference between paper-based and EHR systems, and the common law in relation to health records.

CHAPTER THREE

Medical practice and health records

‘In early modern England, extant records of medical practice range from a handful of cases on a few scraps of paper to the collections of the famous Royal physician, Theodore de Mayerne, who filled more than 3000 pages with a selection of some 1000 of his cases (probably around half) from 1603-53.’²⁰³

3.1 Introduction

Forman and Napier are regarded as the forefathers of modern health record-keeping. Dating back to the 16th century, Forman recorded over ten thousand (10,000) consultations between 1596 and 1603.²⁰⁴ Napier, who learnt the art of record-keeping from Forman, recorded about seventy thousand (70,000) patient consultations between 1597 and the year of his death in 1634.²⁰⁵ A conversation with a patient, observing the patient, examining the patient, collecting bodily fluid and other material specimens, making a clinical diagnosis of the patient’s condition and finally documenting these findings in a health record, remain the cornerstone of daily medical practice. Health records are instrumental tools for the future monitoring and progress of a patient and generally provide legal evidence for their condition; the role of the MP and hospital; and the liability of insurance companies and medical aid administrators.²⁰⁶ In SA, a number of statutes legally protect health records.²⁰⁷ The HPCSA has further provided ethical guidelines on record-keeping for MPs.²⁰⁸

3.2 Definition, composition and ownership of health records

3.2.1 Definition

²⁰³ Casebooks Project History of medical record-keeping available at <http://www.magicandmedicine.hps.cam.ac.uk/on-astrological-medicine/further-reading/history-of-medical-record-keeping> accessed 24 March 2017.

²⁰⁴ Ibid.

²⁰⁵ Casebooks Project *op cit*.

²⁰⁶ See: DJ McQuoid-Mason ‘Medical records and access thereto’ (1996) 15(3) *Medical Law* 499-517.

²⁰⁷ See: The National Health Act 61 of 2003. The Mental Health Care Act 17 of 2002. The Children’s Act 38 of 2005. The Choice on Termination of Pregnancy Act 92 of 1996. The Promotion of Access to Information Act 2 of 2000.

²⁰⁸ HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Guidelines on the keeping of patient records, booklet 9 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%209.pdf accessed 23 July 2017.

A health record is defined as ‘any record made by a medical practitioner at the time of, or subsequent to, a consultation and / or examination or the application of health management for an identifiable person’.²⁰⁹ The HPCSA has accepted this definition.²¹⁰ However, there is no legal definition of a health record in SA. Reference is made to health records in numerous South African statutes but they all lack a clear legal definition.²¹¹ In the US, which has specific legislation that encourages the use of EHR systems, issues have arisen in relation to the expanded nature of health records in the electronic era.²¹²

A health record may embody numerous records from the healthcare service chain, including those from the physician and pharmacy, administrative records, and hospital and outpatient records. They also include video and voice recordings and the numerous electronic images used in diagnostic and therapeutic care of a patient.²¹³ In addition to an operational definition of health records the HPCSA has provided guidance to what constitutes such a record.²¹⁴

3.2.2 The composition of health records

The HPCSA cites the following as constituting a health record:

‘Contemporaneous hand-written notes, included herein are notes from previous and other medical professionals, referral letters, laboratory results, radiological investigations, pathology specimens and slides, electrocardiograph tracings (ECG), audiovisual recordings, photographs and video recordings.’²¹⁵

Insurance medical reports, injury on duty and disability assessment reports, and autopsy reports together with copies of death certificates also form part of health records.²¹⁶

²⁰⁹ A de Klerk ‘The right of patients to have access to their medical records: the position in South African law’ (1993) 12 *Medical Law* 77–83.

²¹⁰ See: HPCSA Booklet 9 (2016) *op cit*.

²¹¹ See: The National Health Act 61 of 2003; The Mental Health Care Act 17 of 2002; The Children’s Act 38 of 2005; The Choice on Termination of Pregnancy Act 92 of 1996; The Promotion of Access to Information Act 2 of 2000.

²¹² AHIMA ‘Fundamentals of the Legal Health Record and Designated Record Set’ available at <http://library.ahima.org/doc?oid=104008#.WHznuRR0Uy4> accessed 16 January 2017.

²¹³ AHIMA *op cit*.

²¹⁴ HPCSA Booklet 9 (2016) *op cit* 1.

²¹⁵ *Ibid*.

²¹⁶ *Ibid*.

Accepting the HPCSA's recommended definition as a legally acceptable one, the following questions arise:

- 1) What aspects of patient data should be included in patient records?
- 2) To what extent should the above be included in patient records?
- 3) To whom should disclosure of confidential health records occur, when EHR or other electronic means are used?

It is submitted that the answers to these questions involve a review of the ownership of an EHR system and the property rights attached therein.

3.2.3 Ownership of electronic health records systems

The South African common law definition of ownership and the rights attached therein were defined in *Glen v Glen*²¹⁷. Ownership has been described as the most complete right a legal subject has in relation to an object, which translates into an absolute and complete entitlement to the property that is owned.²¹⁸ This principle emanated from the legal principle of *nemo plus iuris ad alium transferre potest quam ipse haberet* (no one can transfer more rights than he or she has) and was first applied in *Glatthaar v Hussan*²¹⁹. The entitlement of ownership allows the holder of these rights to use, alienate, vindicate, neglect (can be limited), destroy, possess and encumber the property concerned.²²⁰ However, the ownership of medical information has not been clearly defined in law, and is inconsistent and uncertain.²²¹

There is uncertainty as to whether health records are owned by the patient, medical practitioners, insurers, medical aid administrators, EHR system administrators, or combined ownership or no one. In SA, the HPCSA has advocated a pluralistic system of ownership of health records.²²² In instances where state healthcare services are used, ownership of records is vested in the state and where private medical services are used, in the patient.²²³ Vesting of ownership of written health records still lies

²¹⁷ *Glen v Glen* 1979 (2) SA 1113 (T).

²¹⁸ H Mostert et al *The Principles of the law of Property in South Africa* (2010) 91-92.

²¹⁹ *Glatthaar v Hussan* 1912 TPD 322.

²²⁰ Ownership can be limited by objective law (legislation and neighbour law) or the subjective rights of other persons. See: GJ Pienaar 'Registration of informal Land use rights in South Africa: Giving Teeth to (toothless?) paper tigers' (2000) 3 *TSAR* 442.

²²¹ MA Hall 'Property, privacy, and the pursuit of interconnected electronic medical records.' (2010) 95(631) *Iowa Law Review* 642.

²²² HPCSA Booklet 9 (2016) *op cit*.

²²³ *Ibid*.

with the patient and those entities that have possession of such records and have been entrusted with their safe-keeping.²²⁴

The *Tshabalala-Msimang* case provided some guidance on ownership of health records. However the common law and legislation has not clearly defined ownership of hand-written or electronic health records. Internationally, different legal rules apply in different jurisdictions.²²⁵ In the US, ownership rights to information such as EHR is generally not recognized and the creation of ownership rights to protect privacy has been described as impractical.²²⁶

It is thus submitted that in proposing measures for the use of EHR, cognizance must be taken of the uncertainties concerning the property rights of health records.²²⁷ Compounding the complexity is the added threat, vulnerability and security of systems that store, retrieve or transmit EHR. The differentiation of paper-based and EHR needs to be critically evaluated in relation to these factors, their extent and who should have access to them.

3.3 Electronic health records versus paper-based records

Despite widespread international acceptance and incentives for the use of EHR systems, paper-based and dual-based systems are mainly used.²²⁸ EHR use in SA is

²²⁴ See: *Tshabalala-Msimang and another v Makhanya* 2008 (6) SA 102 (W), hereafter referred to as *Tshabalala-Msimang*. In this case a large private hospital that was trusted with the safe-keeping of records for the patient Tshabalala-Msimang had the records removed or 'stolen' from their secure place of safe-keeping. Tshabalala-Msimang was the Minister of Health and the records were disclosed to the press. See also: Other legislation such as the Promotion of Access to Information Act 2 of 2000 and the Protection of Personal Information Act 4 of 2013. Both have relevant sections on access and protection of personal information. This is further discussed in chapter four.

²²⁵ See: Hall *op cit* 647. See also: *Estate of Finkle* 395 N.Y.S 2d (N.Y. 1977) 344. See further: PV Stearns 'Access to and cost of reproduction of patient medical records: a comparison of state laws' (2000) 21(1) *Journal of legal medicine* 79.

²²⁶ See: ES Pasterneck 'HIPPA in the age of electronic health records' (2010) 41(3) *Rutgers Law Journal* 837. The creation of property rights for healthcare information is not practical due to one of the fundamental rights of ownership, that of alienability. This allows the owner to transfer rights to private and confidential information.

²²⁷ From his own experience and usage of a limited health records system, the writer has found that ownership of health records vests in a private medical aid administrator and an 'opt-in' and 'op-out' clause is attached to disclosure of such records.

²²⁸ See: J Stausberg et al 'Comparing Paper-based with Electronic Patient Records: Lessons Learned during a Study on Diagnosis and Procedure Codes' (2003) 10(5) *Journal of the American Medical Informatics* 470-477.

limited.²²⁹ Paper health records are generally unstructured, consist of loose vocabulary and in many instances lack ICD 10 codes.²³⁰ In contrast, EHR are well-structured, and may include ICD 10 codes that enable easier communication with other medical practitioners and service providers.²³¹

Studies in the US dating back to 2003 that compared paper records with EHR revealed huge gaps in the form of missing information.²³² This issue mainly arises from the unstructured element of paper-based records where the style of recording is at the discretion of practitioners. The length of time that records, paper or electronic, need to be stored is based on statutory law, the common law and the law of contract. The only provision in terms of statutory law that impacts on the time period is the Prescription Act²³³. The HPCSA has recommended the following guidelines:²³⁴

- Children’s records should be kept until they are 21 years of age. Children become majors at 18 years; allow three years for prescription.
- Obstetric patients; keep records until the age of 21 based on the three-year prescription rule.
- Mentally impaired patient; record keeping should be ongoing.
- The MP’s suspicion of a disease entity that presents or manifests later in life, such as asbestosis: record keeping extends until death.
- Statutory obligations against the state: 20 years.

Generally, it is recommended that records should be kept for at least six years on becoming dormant.

There are no statutory rules or specific HPCSA guidelines on electronic health record keeping in SA. It is submitted that given issues such as decreased storage space and

²²⁹ The state healthcare sector uses an EHR system in the Nkosi Albert Luthuli hospital in Durban. The private health care sector uses a limited EHR system by a medical aid administrator that currently operates on an ‘opt-in’, ‘opt-out’ system. The insurance company uses a limited online EHR system, the currently operates on a medical practitioner ‘opt-in’ system.

²³⁰ ICD 10: International Classification of Diseases, 10th classification. This classification is used internationally as a benchmark for the classification of disease entities.

²³¹ See: Stausberg et al *op cit* 470–477.

²³² *Ibid.*

²³³ Act 68 of 1969. The Act provides for various time periods for a debt to prescribe.

²³⁴ HPCSA Booklet 9 (2016) *op cit* 4.

off-site storage of EHR, records should be kept from birth until death and until the deceased estate has fulfilled all statutory obligations.

Dual systems have in the past improved efficiencies to a limited extent. However, this generally depends on the amount and accuracy of the data. Paper-based records have to be reviewed to supplement electronic records for a complete and detailed description, ongoing care and management requirements.²³⁵ Two recording systems that may contain discrepancies pose the risk of mismanagement and litigation. This could defeat the gains made from a management perspective from the speed, accuracy and reliability offered by electronic records in the healthcare sector. Thus, dual systems could add to the increase in medical malpractice litigation in SA.²³⁶ Unfortunately, within the South African common law context of EHR, there are no reported cases, and guidance will have to be obtained from the common law cases on paper records.

3.4 The common law and health records

Tshabalala-Msimang dealt with the unlawful theft of a paper-based file from a private hospital, and the disclosure and publication of the confidential health records of the then Minister of Health, Tshabalala-Msimang. Allegations of alcohol abuse by the minister contained in these records were published in a leading South African newspaper. The court in this case had to decide the following:

- i. Whether the published article violated Tshabalala-Msimang's constitutional right to privacy and dignity.
- ii. Whether the respondent's possession of the health records was unlawful.²³⁷

Prior to dealing with these two questions, Jajbhay J stated that health records are private and confidential, and need to remain as such. He stated the following reason why such information is private:

²³⁵ The writer describes the situation where a limited EHR system is used to access important medical information in an emergency, but due to the limited nature of details on the EHR system, the MP is forced to review the detailed paper record.

²³⁶ See: Pepper & Slabbert *op cit* 29.

²³⁷ NHA, section 17

‘Individuals value the privacy of confidential medical information because of the vast number of people who could have access to the information and the potential harmful effects that may result from disclosure. The lack of respect for private medical information and its subsequent disclosure may result in fear of jeopardizing an individual’s right to make certain fundamental choices that he/she has a right to make. There is therefore a strong privacy interest in maintaining confidentiality.’²³⁸

South African courts have a long established common law history of protecting confidentiality, dating back to before the constitutional era and the enactment of the NHA. The *locus classicus* in this regard in medical practice is *Jansen Van Vuuren v Kruger*.²³⁹ Aspects of privacy and confidentiality emanating from this case have now become entrenched in the BOR in our Constitution²⁴⁰, protected by the NHA and the guidelines provided by the HPCSA.

With regard to the NHA²⁴¹, the court analysed the following sections:

- 1) The objects contained in section 2;
- 2) Confidentiality contained in section 14;
- 3) Access to health records contained in section 15; and
- 4) Protection of health records contained in section 17 of the Act.²⁴²

In determining the lawfulness of the possession of the minister’s health records, Jajbhay J applied the above sections of the NHA. He held that continued possession was unlawful, and that they should be returned to the lawful owner or the entity in charge of their safe-keeping. The court granted a punitive cost order against the respondents jointly and severally and stated that they were unlawfully in possession of Tshabalala-Msimang’s health records. The importance of this case in the South African jurisprudence of health records is that re-establishes three legal principles, *inter alia*, that of:

1. The common law principles of privacy, confidentiality and dignity;

²³⁸ *Tshabalala-Msimang* supra 27.

²³⁹ See: *Jansen Van Vuuren v Kruger* supra. See also: *Tohill v Forster* 1925 TPD 857.

²⁴⁰ The Constitution of the Republic of South Africa, 1996.

²⁴¹ Act 61 of 2003.

²⁴² See: PA Carstens ‘Access to medical records without consent of the patient and the publication thereof in the public domain: Issues of privacy, dignity, freedom of expression and the public interest. *Tshabalala-Msimang and Medi-Clinic Ltd v Makhanya* 2008 3 BCLR 338 (W)’ (2008) 29(2) *Obiter* 291-301. See also: Carstens & Pearmain *op cit* 943.

2. The constitutional principles of dignity, privacy and freedom of expression; and
3. The statutory principles in the NHA on health records, and their confidentiality, access and protection.

However the constitutional rights of the applicant proved more complex because the *Tshabalala-Msimang* case also highlighted the issue of two competing constitutional rights, freedom of expression and the right to dignity. Jajbhay J limited Tshabalala-Msimang's right to dignity in favour of freedom of expression.²⁴³ He held that it was in the public interest that the publication of such information be allowed.²⁴⁴

Jajbhay J stated that the term 'public interest' was a mysterious concept, which he likened to a 'battered piece of string charged with elasticity, impossible to measure or weigh'.²⁴⁵ He added that there is no census on the term 'public interest' but acknowledged its existence and application in this case, citing democracy, politics and debates as reasons for its inclusion.²⁴⁶ He further questioned the term 'public figure' and quoted the definition used by McQuoid-Mason²⁴⁷. Carstens states that the judgment was a sterling example of post-constitutional jurisprudence that balanced and transcended the previous divide of private and public law.²⁴⁸

However Carstens²⁴⁹ further argued that the court's judgment in the *Tshabalala-Msimang* case lacked a counterargument, namely:

1. If and under what circumstances a legal duty may arise for a medical professional to disclose private and confidential health information without the consent of the patient?²⁵⁰

²⁴³ See: *Tshabalala-Msimang* supra 55. The constitutional rights and aspects of health records are further discussed in chapter four.

²⁴⁴ Ibid.

²⁴⁵ See: *Tshabalala-Msimang* supra 37.

²⁴⁶ Ibid.

²⁴⁷ See: DJ McQuoid-Mason 'Invasion of Potency?' (1973) 90(23) *SALJ* 29. McQuoid-Mason submits that the test whether a person is a public figure should be: Was he by his personality, status or conduct exposed himself to such a degree of publicity as to justify intrusion into, or a public discourse on, certain aspects of his private life? However, non-actionable intrusions on his privacy should be limited to those that are in the public interest or for the public benefit, so that unjustified prying into personal affairs, unrelated to the person's public life, may be prevented.

²⁴⁸ See: Carstens *Obiter* (2008) *op cit* 300.

²⁴⁹ Ibid.

2. If and under what circumstances the press may disclose private and confidential health information without the consent of the patient?²⁵¹

McQuoid-Mason (2007) argues for the disclosure of the health status of public figures where public activities are relevant, and when it is for the benefit of public truth or a privileged occasion allows for such disclosure.²⁵²

The writer agrees with Carstens' counterargument and submits that the following should be added to the question of disclosure of public figures' health records on EHR systems:

1. What added measures should be taken, if necessary, for disclosure of a public figure's health records when using an EHR system?²⁵³

Statutory exemptions exist for the disclosure of health records without the patient's consent.²⁵⁴ Apart from these exceptions, the common law has recognized a number of defences for disclosing confidential health records without a person's consent. Statutory law further allows requests for access to information for the protection of a right.²⁵⁵ Similarly, statute has been recently enacted for the protection of personal information.²⁵⁶

3.5 Security of electronic health records

The transition from a paper to an EHR system is fraught with risk.²⁵⁷ Hacking and extortion of electronic health record servers is a common cybercrime in the US.²⁵⁸

²⁵⁰ See: Carstens *Obiter* (2008) *op cit* 301. See also: *Tarasoff v Regents of the University of California* 83 ALR 3 rd 1166 (Cal 1976). It was held in this case that there is a legal duty on a health professional to warn endangered parties.

²⁵¹ See: Carstens *Obiter* (2008) *op cit* 301. See: *NM and Others* *supra*, This case involved the disclosure of the HIV status of persons that participated in a clinical trial and the court held that consent should have been obtained for the publication of their names in the book.

²⁵² DJ McQuoid-Mason 'Disclosing the health status of public figures: Privacy versus public interest – when may doctors make public disclosure?' (2007) 97(5) *SAMJ* 334-337.

²⁵³ A public figure will generally attract more interest and in many instances an increased risk of theft and public disclosure of such information.

²⁵⁴ See: NHA, reference and discussion on the relevant section is in chapter four. Similarly, the HPCSA guidelines are discussed in chapter four.

²⁵⁵ See: The Constitution of the Republic of South Africa, 996. See also: section 32; the Promotion to Access of Information Act 2 of 2000: For further discussion see chapter 4.

²⁵⁶ Protection of Personal Information Act 4 of 2013.

²⁵⁷ Pasterneck *op cit* 846.

²⁵⁸ See: G Gantt 'Hacking health care: Authenticating security in the age of meaningful use' (2014) 27(232) *Journal of Law and Health* 232.

Generally, criminals gain unauthorized access to secure data servers, remove or encrypt the data, and only provide access passwords once a ransom is paid. LinkedIn²⁵⁹ was hacked in 2012.²⁶⁰ The hacked email addresses and passwords that allowed access to users' personal information were then placed on social electronic media websites in Russia at the time and again in 2016.²⁶¹

More recently, in May 2017 a UK hospital was brought to a complete standstill due to a 'ransomware virus' resulting in following:

- a) 'General disarray in at least sixteen hospitals;
- b) Cancelled appointments for non-urgent patients;
- c) Cancellation of non-urgent operations;
- d) Basic health records were inaccessible; and
- e) Doctors had to resort to the use of pen and paper to compile records.'²⁶²

These unlawful acts have the potential to invade the privacy and impair the dignity of affected users. SA confronts similar risks to those exposed in the LinkedIn and 'ransomware virus' cases. These criminal acts pose a threat to privacy, slow the uptake of EHR and have resulted in avoidance of highly sensitive medical data being placed on EHR systems.²⁶³

Mobile devices such as smartphones, iPads and laptops are now used to transmit sensitive medical information such as X-Rays, laboratory results and ECGs. This has raised questions about whether such technology should be used in the medical sector and whether security measures should be tightened in terms of access.²⁶⁴ Heightened security measures have been used in financial sectors such as banking.²⁶⁵ In the US, it has been suggested that these should be adopted by legislative amendments to

²⁵⁹ A social networked that has a business focused 'digital platform' that connects people.

²⁶⁰ See: I Paul 'Update: LinkedIn Confirms Account Passwords Hacked' available at <http://www.pcworld.com/article/257045/security/6-5m-linkedin-passwords-posted-online-after-apparent-hack.html> accessed 29 March 2017.

²⁶¹ Pagilery *op cit*.

²⁶² R Brandom 'UK hospitals hit with massive ransomware attack: Sixteen hospitals shut down as a result of the attack' available at <https://www.theverge.com/2017/5/12/15630354/nhs-hospitals-ransomware-hack-wannacry-bitcoin> accessed 13 June 2017.

²⁶³ Gantt *op cit* 232.

²⁶⁴ Gantt *op cit* 240.

²⁶⁵ Gantt *op cit* 247.

accommodate industry-wide minimum benchmarks for security standards²⁶⁶ and should encompass the following:

1. 'Administrative safeguards that include a risk assessment and policy formulation for employees to follow;
2. Physical safeguards which include authorized access by certain personal that have granular control over the system and data;
3. Technical safeguards with specialized measures for authentication and access to the computer servers that store the electronic records.'²⁶⁷

It is submitted that although EHR implementation and use is in its infancy in SA, adopting a security benchmark could prevent security issues similar to those faced in the US and UK.

In SA, various pieces of legislation offer little guidance, security and protection measures for EHR systems.²⁶⁸ While the POPI²⁶⁹ prohibits the processing of personal information,²⁷⁰ it is submitted that cyberspace transcends physical and jurisdictional boundaries, making the application of such legal measures impractical in most instances. The alternative is to formulate legal and ethical measures that will avoid unlawful and unethical acts or omissions.

3.6 Conclusion

Globally, EHR gives rise to many unresolved issues. These include uncertainty in terms of its proper legal definition, ownership, vulnerability, and the risk of breaches of security and their consequences.²⁷¹ Despite these drawbacks, the healthcare industry is forced to accept, use and engage with these ever-evolving forms of electronic record keeping.²⁷² The central requirement is that the information electronically stored, communicated, transmitted and retrieved from these databases is private and confidential and needs to be protected. Chapter four analyzes South African statutory law and the HPCSA's ethical guidelines.

²⁶⁶ Ibid.

²⁶⁷ Gantt *op cit* 244-245.

²⁶⁸ See: The NHA 61 of 2003; Promotion to Access of Information Act 2 of 2000; Electronic Communications and Transaction Act 25 of 2002; Choice on Termination of Pregnancy Act 92 of 1996; and the POPI Act 4 of 2013.

²⁶⁹ The POPI, Act 4 of 2013

²⁷⁰ POPI sections 26 and 32. Further discussion in chapter four.

²⁷¹ See: 3.2 above: Definition, composition and ownership of health records. See also: HPCSA booklet 14. See further: Pasterneck *op cit* 846.

²⁷² See: Pasterneck *op cit* 839.

CHAPTER FOUR

Statutory law: Medical practice, electronic health records use and security

‘The state must take reasonable legislative and other measures, within its available resources, to achieve a progressive realisation of each of these rights.’²⁷³

4.1 Introduction

Prior to the democratic constitutional era, health records consisting of private and confidential information were protected under the common law.²⁷⁴ In *Jansen van Vuuren v Kruger*, the Appellate Division confirmed that confidential medical information may only be disclosed between MPs under limited circumstances.²⁷⁵ In *Castell*: the Cape High Court set the South African legal standard for informed consent.²⁷⁶ The Interim Constitution also introduced an important and fundamental meaning of some of the common law principles of privacy and dignity.²⁷⁷ The BOR in the final Constitution set the highest legal standard.²⁷⁸ The codification of many of the common law principles²⁷⁹ now protects the confidential nature of health records and their preservation.²⁸⁰ This chapter discusses the Constitution, statutory law, and the HPCSA guidelines.

4.2 The Constitution

The Interim Constitution²⁸¹ recognized human dignity at its epicenter. In the *S v Makwanyane* case,²⁸² O’Regan J stated that ‘recognition and protection of human dignity is the touchstone of the new political order and is fundamental to the new Constitution.’ Similarly in *Carmichele v Minister of Safety and Security*²⁸³, human dignity was described as being central to the Constitution’s impartial, normative value system. Within this system, ‘dignity’ has become a fundamental aspect of a person’s self-worth.

²⁷³ The Constitution of the Republic of South Africa, 1996.

²⁷⁴ See: *Jansen van Vuuren v Kruger* supra.

²⁷⁵ *Jansen van Vuuren v Kruger* supra 37-38.

²⁷⁶ *Castell* supra.

²⁷⁷ See : *S v Makwanyane* 1995 (3) SA 391 (CC).

²⁷⁸ See: The Constitution of the Republic of South Africa, 1996, section 39(3). The BOR does not deny the existence of any other rights or freedoms recognized or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.

²⁷⁹ See: *Castell* supra. The principles of informed consent are now codified in the NHA, in sections 13; 14; and 15.

²⁸⁰ See: NHA.

²⁸¹ The Interim Constitution of the Republic of South Africa, 1993.

²⁸² See: *S v Makwanyane* supra 329.

²⁸³ *Carmichele v Minister of Safety and Security* 2001 (4) SA 938 (CC) 56.

The origins of self-worth or intrinsic worth can be traced to Kantian moral philosophy concepts.²⁸⁴ However, dignity has been described as having a broad meaning that encompasses many different values.²⁸⁵ While it is difficult to provide a precise definition of this concept, it is clear that, constitutionally, protection of dignity requires that the individual worth of all members of society is valued.²⁸⁶

Section 10 of the Constitution states that ‘everyone has inherent dignity and the right to have their dignity respected and protected’. This includes not unlawfully disclosing patients’ health records stored on an EHR system or by electronic means.²⁸⁷ Dignity is a justiciable and enforceable right that is central to all other fundamental rights in the BOR as well as to any limitations enquiry.²⁸⁸

The constitutional right to privacy states that ‘everyone has the right to privacy, which includes the right not to have the privacy of their communications infringed’, and is an important right to consider when medical information is transmitted, communicated or stored using an EHR system.²⁸⁹ Generally, this is infringed when a person’s home or property is unlawfully searched, or when their possessions are seized or communications intercepted.²⁹⁰ Privacy at common law can be invaded in numerous instances, including unlawfully publishing a person’s photograph without their consent²⁹¹ or, as in the case of *NM v Smith*,²⁹² disclosing in a book that someone

²⁸⁴ See: O Schachter ‘Human Dignity as a Normative Concept’ (1983) 77(4) *American Journal of International Law* 848. It is stated that respect for human dignity is grounded in the Kantian injunction to treat every human being as an end, not as a means; individuals are not to be perceived or treated merely as instruments or objects of the will of others. See also: *S v Dodo* 2001 (3) SA 382 (CC) 38: ‘Human beings are not commodities to which a price can be attached; they are creatures with inherent worth and infinite worth; they ought to be treated as ends in themselves, never merely as means to an end.’

²⁸⁵ *Le Roux v Dey* 2011 (3) SA 274 (CC) 138.

²⁸⁶ See: *National Coalition for Gay and Lesbian Equality v Minister of Justice* 1999 (1) SA 6 (CC) 29. (Ackermann J). *Nyathi v MEC for the Department of Health, Gauteng* 2008 (5) SA 94 (CC) 45: requires recognition of worth and importance of every human being.

²⁸⁷ The Constitution, 1996, section 10.

²⁸⁸ See: *Dawood v Minister of Home Affairs* 2000 (3) SA 936 (CC) 35. See further: the discussion on the link between privacy and dignity in *Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd: In re Hyundai Motor Distributors (Pty) Ltd v Smit* NO 2001 (1) SA 545 (CC)18: The more the law intrudes upon the intimate personal sphere, the more intensely the right to privacy ought to be protected ; this understanding of privacy flows from the value placed on human dignity.

²⁸⁹ The Constitution, 1996, section 14(d).

²⁹⁰ *Director of Public Prosecutions: Cape of Good Hope v Bathgate* 2000 (2) SA 535 (C) supra 82.

²⁹¹ See: *O’Keeffe v Argus Printing and Publishing Co Ltd* 1954 (3) SA 244 (C) 247F–249D. The Argus newspaper published a photograph of O’Keeffe (with her consent) firing a gun; the same photograph was used without her consent in an advertisement for guns and ammunition. Also see: *Kidson v SA*

is HIV positive. Although the *NM v Smith* case principle involved the publication of the research subjects' HIV status, the principles are broad and encompass all medical data or information that attracts an interest in privacy. Lacking any constitutional challenge, the common law has been horizontally applied in most instances of a breach of privacy.²⁹³ A breach of the right to dignity has been dealt with in a similar manner.²⁹⁴

Another important constitutional right that our courts have dealt with in relation to health records is the right to freedom of expression.²⁹⁵ Section 16 (1) (a) of the Constitution has been interpreted to mean that freedom of the press, and other media, can in certain specific instances trump competing constitutional rights such as dignity.²⁹⁶

An individual's health records commence at birth and extend beyond death. A child is regarded as any person below the age of 18.²⁹⁷ Section 28(2) of the Constitution states that, 'a child's best interests are of paramount importance in every matter concerning the child'; this has a broad meaning in matters concerning the principle of 'the best interests of the child'.²⁹⁸ The Constitutional Court has generally pronounced on this

Associated Newspapers Ltd 1957 (3) SA 461 (W): Unauthorised publication in a newspaper of photograph of nurses with the caption '97 lonely nurses want boyfriends'. See further: *MEC for Health, Mpumalanga v M-Net* 2002 (6) SA 714 (T): Broadcast of 'hidden camera' video material showing alleged medical malpractices and mistreatment of patients in a public hospital in violation of privacy; justified on the grounds of public interest. Finally, see: *Greeff v Protection 4U h/a Protect International* 2012 (6) SA 392 (GNP): Publication of video of 'Kamp Staalraad' involving the Springbok rugby team engaged in demeaning rituals; though filmed with the players' consent, such consent did not extend to publication of the video.

²⁹² *NM v Smith* supra 41. This case should be differentiated from the *Jansen van Vuuren* case that involved a breach of confidentiality.

²⁹³ *Dikoko v Mokhatla* 2006 (6) SA 235 (CC) 91: The common law remedies that vindicate constitutionally entrenched rights constitute appropriate relief in terms of s 38 for the breach of those rights.

²⁹⁴ *Dikoko v Mokhatla* supra 91.

²⁹⁵ See: *Tshabalala-Msimang* supra. In this case the court had to deal with three important constitutional rights; the right to dignity; the right to privacy and the right to freedom of expression. The court held that the right to freedom of the press could trump the right to dignity and privacy. It based its decision on the fact that Tshabalala-Msimang was a public figure and that it was in public interest to publish information concerning her health records.

²⁹⁶ See: *Tshabalala-Msimang* supra.

²⁹⁷ The Children's Act 38 of 2005, section 1: This definition places the courts as the upper guardians of children subject to the 1996 Constitution and other applicable law that allows a child to make decisions on their healthcare.

²⁹⁸ See: The Constitution of the Republic of South Africa, 1996, section 28(2). Also see: The Children's Act 38 of 2005, section 9. This section is a replication of section 28(2) of the 1996 Constitution.

principle in cases relating to the context of the family or parental care.²⁹⁹ In *S v M* the meaning of ‘the child interests are of paramount importance’ was expanded to include the best interests of the children, when their primary caregiver (a single mother) faced a short term of imprisonment.³⁰⁰

The ‘best interests of the child’ in relation to healthcare was considered in *Christian Lawyers’ Association of South Africa v Minister of Health*.³⁰¹ The Constitutional Court also dealt with children’s right to privacy, dignity and freedom of expression in *Johncom Media Investments v M*³⁰² and declared section 12 of the Divorce Act of 1979 to be unconstitutional and not in the best interests of the child.³⁰³

The Constitution allows for the limitation of rights set out in the BOR.³⁰⁴ Jajbhay J limited the right to dignity in *Tshabalala-Msimang*.³⁰⁵ He expressed the following view in support thereof:

- i. ‘[J]ust because we possess rights, does not mean that we must exercise them to the hilt at every opportunity.
- ii. Though we enjoy freedom of expression, we would be ill-advised to celebrate it by vilifying each other on the slightest pretext.³⁰⁶

It is submitted that the *Tshabalala-Msimang* case should have been challenged in an appeal. Constitutional rights are important; the right to dignity and privacy are important personality rights, and the right to freedom of expression and the best interests of the child are important constitutional rights when EHR and electronic

²⁹⁹ See: *Bannatyne v Bannatyne* 2003 (2) SA 363 (CC): An obligation by parents to properly care for their children, obligation by the state to ensure appropriate care by providing the necessary legal administration in relation to the payment of maintenance. See also: *S v M* 2008 (3) SA 232 (CC): The court considered the right to family and parental care where the children’s primary caregiver was imprisoned. See also *C v Department of Health and Social Development, Gauteng* 2012 (2) SA 208 (CC): Found lack of provision for automatic review of the removal of children from their parents to be an unconstitutional infringement of their best interests.

³⁰⁰ *S v M* 2008 (3) SA 232 (CC) supra 16. In terms of the Criminal Procedure Act 51 of 1977, sentencing in terms of s 276(1)(i) allowed one-sixth of the prison term to be served.

³⁰¹ See: *Christian Lawyers’ Association of South Africa v Minister of Health* 2005 (1) SA 509 (T).

³⁰² See: *Johncom Media Investments v M* 2009 (4) SA 7 (CC).

³⁰³ See: L Albertus ‘Has the Balance Been Struck? The Decision in *Johncom Media Investments Limited v M* 2009 (4) SA 7 (CC)’ (2011) 14(1) Potchefstroom *Electronic Law Journal* 216-234.

³⁰⁴ See: The Constitution of the Republic of South Africa, 1996, section 36(1). These rights may be limited in terms of a law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including:

the nature of the rights :e) Less restrictive means to achieve the purpose (s 36 (1)).

³⁰⁵ *Tshabalala-Msimang* supra 55.

³⁰⁶ *Ibid.*

means are used to store, access and transmit health records. Linked to these constitutional rights are various statutory laws.

4.3 Statutory Law

4.3.1 The National Health Act³⁰⁷

The NHA provides the most comprehensive statutory obligation imposed on healthcare professions for the control, storage, preservation, access to and disclosure of confidential health records, amongst other important provisions.³⁰⁸ Chapter two of the Act makes provision for the user's consent to be obtained and creates a duty for reasonable steps to be taken to obtain their consent.³⁰⁹ Important sections of the NHA in relation to health records include the following:

- Section 13 places an obligation on a person in charge of a health establishment to keep records;
- Section 14 places an added obligation of confidentiality regarding a person's status, stay or treatment by a health establishment.
- Section 14(2) provides for exceptions to the non-disclosure of confidential information, namely:
'Subject to section 15, no person may disclose any information contemplated in section 14(1) unless:
 - a) the user consents to that disclosure in writing;
 - b) a court order or any law requires that disclosure; or
 - c) non-disclosure of the information represents a serious threat to public health.'
- Section 15 provides an exception to the non-disclosure rule in that employees and service providers that have access to health records are allowed to disclose these confidential records, provided it is for a 'legitimate purpose within the scope and ordinary course of his or her duties and in the interest of the user'.
- Section 16 (1) (a) allows access to health records for treatment purposes and with the user's consent.

³⁰⁷ See: NHA.

³⁰⁸ See: NHA.

³⁰⁹ See: NHA, section 7(1) & 7(2).

- Section 17(1), places an obligation on the ‘person in charge of a healthcare establishment where records are stored, preventing unauthorized access to the storage facility or system by which the records are kept’.
- Section 17(2) (a) to (j), specifies when there is a breach of the legal obligations imposed by the NHA and the duties in s 17(1), which are spelled out in the following sections:

Section 17(2):

(h) specifically prohibits unauthorized access to records or a records system and the interception of information from one person to another or from one system to another.

It is submitted that, in general, this will prohibit any form of unauthorized interception and access to any communication, transmission and storage system that is operated when electronic means is used in medical practice.

Section 17(2):

(i) prohibits the unauthorized connection of ‘any part of a computer or other electronic system on which records are kept’.

(j) prohibits unauthorized modification or impairment of the operation of:

(i) ‘any part of the operating system of a computer or other electronic system on which a user’s records are kept; or

(ii) any part of the programme used to record, store or retrieve or display information on a computer or other electronic system on which the user’s records are kept.’

It is submitted that because of the lack of South African case law on EHR, the *Tshabalala-Msimang* case remains the most persuasive case on health records.

4.3.2 The Mental Health Care Act³¹⁰

A person must have the mental capacity to understand and appreciate the consequences of granting consent for the disclosure of health records.³¹¹ This places an obligation on an MP to determine whether the person is mentally competent or incompetent prior to obtaining such consent.³¹² The Mental Health Care Act deals with a number of provisions on, *inter alia*, informed consent, confidentiality,

³¹⁰ Act 17 of 2002.

³¹¹ Dhai and McQuoid-Mason (2011) *op cit* 72.

³¹² Dhai and McQuoid-Mason (2011) *op cit* 81.

disclosure and access to records.³¹³ It is submitted that these provisions apply equally when EHR and electronic means are used.

4.3.3 The Children's Act³¹⁴

The principle of a child's best interests being of paramount importance applies to all aspects of healthcare services.³¹⁵ As upper guardians of minor children, the courts robustly apply this principle.³¹⁶ The Constitutional Court applied the principle of the child's right to privacy and dignity in *Johncom Media Investments v M*³¹⁷ and limited the right to freedom of expression. The Act made sweeping changes to the following areas involving healthcare and the rights of children.³¹⁸ The changes that are important to EHR include *inter alia*, that of consent, confidentiality, HIV testing and disclosure.

On the question of consent, the Children's Act provides the following:

- a) A child of twelve (12) years of age can consent to medical and surgical treatment.³¹⁹
- b) A child of 12 years of age can access contraceptives.³²⁰
- c) A child can consent independently from the age of 12 years to an HIV test.³²¹

³¹³ See: Dhali & McQuoid-Mason (2011) *op cit* 81- 82. See also: The Mental Health Care Act, Act 17 of 2002. Section 13(1) states that, in terms of disclosure of information in relation to mental healthcare patients, '[a] person or a health establishment may not disclose any information which a mental healthcare user is entitled to keep confidential in terms of any other law.' Section 13(2) states that '[d]espite subsection (1), the head of the national department, a head of provincial department or the head of a health establishment concerned may disclose such information if failure to do so would seriously prejudice the health of the mental health care user or of other people'.

³¹⁴ The Children's Act 38 of 2005.

³¹⁵ See: The Constitution, 1996, section 28(2). See also The Children's Act 38 of 2005, section 9.

³¹⁶ See: *Hay v B* 2003 (3) SA 492 (W): An application was brought to override parental refusal to consent to an urgent blood transfusion. The parents' refusal was based on religious grounds. The court held that the parents' views had to be considered but their private beliefs should not override the child's right to life. See also Z Venter 'Girl (6) to have brain operation despite dad's refusal' *Pretoria News* (30/10/2006). Z Venter 'Tug-of-war over teen stricken by cancer' *Pretoria News* (26/01/2007).

³¹⁷ *Johncom Media Investments v M* *supra*. In this case the right to dignity and privacy of a child was compared to the constitutional right to freedom of expression. The case related to a divorce matter and the court held that the right to freedom of expression could be limited.

³¹⁸ See: A Strode C Slack Z Essack 'Childs consent in South Africa: Implications for researchers , service providers and policy makers' (2011) *SAMJ* 101(9) 602-604.

³¹⁹ See: Children's Act 38 of 2005. Section 129(2): (a) 'allows a child of 12 years of age to consent to their own medical treatment; provided that they: (b) have sufficient maturity and mental capacity to understand benefits, risks, social and other implications of the treatment'. Section 129(3) 'allows a child of 12 years of age to consent to their own surgical operation; provided that they have sufficient maturity and mental capacity to understand benefits, risks, social and other implications of the treatment'; the child is duly assisted by his or her parent or guardian.

³²⁰ See: Children's Act 38 of 2005. Section 134(3) provides for a statutory confidentiality obligation to be maintained when a child accesses condoms, contraception or a contraceptive device.

d) A child's HIV / AIDS status is confidential.³²²

Despite the Act's progressive advancement of the rights of children, it is silent on the use of EHR and electronic means in relation to children. The common law principles apply when contracting with a minor.³²³ It is asserted that a child aged 12 and over who is legally competent in terms of the Children's Act, should contract and consent with a MP for the use of EHR and electronic means.

4.3.4 The Choice on Termination of Pregnancy Act³²⁴

Irrespective of her age, a female can consent to and undergo termination of pregnancy.³²⁵ The CTOP Act places an obligation on an MP or midwife to advise the minor to consult with a parent, guardian, family member or friend, but if she refuses the service should not be denied.³²⁶ The Act further places a duty on the MP, registered midwife or the person in charge of the facility to collate (without the names and addresses of a person), and forward the information in the prescribed manner, by registered post to the Director-General of Health.³²⁷

³²¹ See: Children's Act 38 of 2005, section 130.

³²² See: Children's Act 38 of 2005. Section 133(1), specifically re-enforces the common law in relation to confidentiality of the HIV/AIDS status of children and states that 'no person may disclose the fact that a child is HIV positive without the consent of the child or an authorised person, except: Within the scope of that person's powers and duties in terms of the Act or any other law; When necessary for the purposes of carrying out the provisions of the Act; For the purpose of legal proceedings; or in terms of an order of court.' See also: DJ McQuoid- Mason 'The effect of the new Children's Act on consent to HIV testing and access to contraceptives by children' (2007) 97(12) *SAMJ* 1252-1253.

³²³ See: Strode et al *op cit* 602-606. The Children's Act 38 of 2005 made changes in terms of the common law and now enables a child to contract for medical services, based on the nature and circumstances of the medical or surgical treatment sought.

³²⁴ The Choice on Termination of Pregnancy Act 2 of 1996, as amended. Hereafter referred to as the CTOP Act

³²⁵ See: CTOP Act. Section 5 (2) states that '[n]otwithstanding any other law or the common law, but subject to the provisions of subsections (4) and (5), no consent other than that of the pregnant woman shall be required for the termination of a pregnancy'. See also: Strode et al *op cit* 247. See further: DJ McQuoid-Mason 'Termination of pregnancy and children: Consent and confidentiality issues' (2010) 100(1) *SAMJ* 213.

³²⁶ See: CTOP Act. Section 5 (3) states that '[i]n the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be, shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is terminated: Provided that the termination of the pregnancy shall not be denied because such minor chooses not to consult them'.

³²⁷ See: CTOP Act, section 7(1) - 7(5).

The CTOP Act creates a positive duty for the keeping of health records and criminalizes failure to keep such records.³²⁸ The constitutionality of the CTOP Act was dealt with in *Christian Lawyers' Association of South Africa v Minister of Health*³²⁹. However issues such as record keeping, confidentiality, consent and disclosure of such confidential information were not addressed in this case.³³⁰ More precisely, the Act is silent on the use of EHR or electronic means. It is submitted that termination of pregnancy data should only be disclosed when consented to, and when highly secured EHR systems are used. It is further submitted that the patient should have limited control over termination of pregnancy information on the EHR system, thus allowing the patient to either grant or deny MPs access to this specific information.

4.3.5 The Promotion of Access to Information Act³³¹

The PAIA does not specifically refer to the terms confidentiality or consent. However reference is made to 'records' in numerous sections.³³²

Section 30(3)(a) of the PAIA states:

'[I]f the information officer is under the impression that disclosing the record will harm the person, adequate counseling must be arranged with a counselor and the counselor must be given access to the record. Disclosure must be made after counseling and not refused, if deemed by the counselor that disclosure would not cause harm to the person.'³³³

The information officer is responsible for controlling access to records. It is submitted that this also applies to records on EHR systems. If harm is anticipated, access to such records should be restricted until the requirements of this section of the PAIA have been met.

Section 60(1)(b) of the PAIA requires the person in charge of health or other records, to consult with a nominated MP if serious physical or mental harm might be

³²⁸ See: CTOP Act, section 10(1). Persons found guilty and convicted, could be liable for a fine or imprisonment for a period not exceeding 10 years.

³²⁹ 2005 1 SA 509 (T).

³³⁰ See: *The Christian Lawyers' Association v Minister of Health* 2005 (1) SA 509 (T).

³³¹ The Promotion of Access to Information Act 2 of 2000 hereafter referred to as the PAIA.

³³² PAIA, section 30(3)(a); sections 60(1)(b) & 60(2)(a).

³³³ PAIA, section 30(3)(a).

anticipated, before the record is disclosed.³³⁴ It is submitted that a patient's physical and mental health information needs to be assessed and scrutinized prior to such information being stored or transmitted on an EHR system or being transmitted via electronic means. Information that may cause harm should be subject to restrictive and security measures.

4.3.6 The Consumer Protection Act³³⁵

A patient is included in the definition of a 'consumer'.³³⁶ The CPA introduced two significant changes to the area of medical law and EHR:

- 1) Firstly, the use of exemption or exclusion clauses in relation to medical contracts; and
- 2) Secondly, the no faulty liability.³³⁷

The CPA prohibits the imposition of exemption clauses or unfair, unreasonable or unjust terms that exclude liability by a supplier.³³⁸ Section 48(2) lists these exclusions as follows:

- a) An excessively one-sided term that favours any other person except the consumer.
- b) Transactional terms or agreement, that are so adverse to the consumer as to be inequitable.
- c) The consumer relied on false, deceptive or misleading representations or an opinion statement provided by the supplier or on his behalf, to the consumer's detriment.
- d) The 'unfair, unreasonable, unjust or unconscionable' terms, /conditions or notice in the transaction or agreement were not drawn to the attention of the consumer.³³⁹

³³⁴ PAIA, section 60(1)(b).

³³⁵ Act 68 of 2008.

³³⁶ CPA, section 1.

³³⁷ D J McQuoid-Mason (2012: *SAJBL*) *op cit* 65.

³³⁸ See: The CPA, section 48. See also: McQuoid-Mason (2012: *SAJBL*) *op cit* 65.

³³⁹ See: The CPA, section 48(2). Based on his experiences, the writer notes that an exclusion clause applies in patient/medical aid administrator contracts for the disclosure of medical information on an EHR system. 'You also agree that neither Discovery nor the Discovery Group of Companies will be liable for damages or loss arising out of: reliance placed on information contained in the EHR Summaries; suggestions and/or opinions contained in the EHR Summaries; unlawful and unauthorised access to information in the EHR Summaries; unlawful and authorised disclosure of information in the EHR Summaries; interrupted, delayed or failed communication.'

Exemption clauses used in the healthcare sector either exclude or limit liability on one or more persons or entities and their efficiency depends on the wording of the contract.³⁴⁰ It is submitted that a contract for the use of EHR and electronic means must be compliant with the provisions of section 48 of the CPA.³⁴¹

Section 49(1) of the CPA lists the following notices and provisions that must be drawn to the consumer's attention:

- a) 'Limit in any way the suppliers' liability or risk or any other person for any cause;
- b) Constitutes an assumption of risk or liability by the consumer;
- c) Impose an obligation on the consumer to indemnify the supplier or any other person for any cause;
- d) An acknowledgement of any fact by the consumer.³⁴²

It is submitted that the CPA, specifically in terms of this section, obliges a person in control of an EHR system to draw a patient's attention to the risks associated with disclosure of such information when electronic means are used. The consequences of indemnifying a supplier should be explained to the patient.³⁴³

4.3.7 The Electronic Communications and Transactions Act

SA's quest for a technologically advanced paperless healthcare system confronts certain legal challenges.³⁴⁴ In order to achieve an electronic equivalent of paper records, a measure of neutrality has been codified in SA.³⁴⁵ Electronic signatures form part of this transformation and are used in EHR systems.³⁴⁶ Their use, which is codified in the ECTA, and its relation to international benchmarks have been the

³⁴⁰ See: *Afrox Health Care* (SCA) supra. See also: *Durban's Water Wonderland Pty (Ltd) v Botha* 1999 (1) SA 982 (SCA). See further: *Burger v Medi-Clinic* Unreported Judgment Witwatersrand Local Division (1999).

³⁴¹ cf : note 338 above.

³⁴² CPA, section 49(1). See also: *Durban's Water Wonderland Pty (Ltd)* (SCA) supra.

³⁴³ Persons in charge of an electronic health record system include medical professionals, hospital administrators, medical aid service providers and insurance companies.

³⁴⁴ See: SL Snail 'Electronic contracts in South Africa- A comparative analysis' (2008) *Journal of Information Law and Technology* available at http://go.warwick.ac.uk/jilt/2008_2/snail accessed 19 February 2017. See also: L Swales 'The regulation of electronic signatures: Time for review and amendment' (2015) *SALJ* 15 (2) 258.

³⁴⁵ See: *Ketler Investments CC t/a Ketler Presentations v Internet Service Providers' Association* 2014 (2) SA 569 (GJ) 30. See also: Swales *op cit* 258. See further: The Electronic Communications and Transactions Act 25 of 2002, section 2(1) (a): 'recognise the importance of the information economy for the economic and social prosperity of the Republic' and section 2(1) (f): 'promote technology neutrality in the application of legislation to electronic communications and transactions.'

³⁴⁶ See: L Swales *op cit* 258. See also: Snail *op cit*.

subject of academic debate.³⁴⁷ The writer accepts the ECTA in its current form. Thus, electronic signatures are equivalent to a written signature.³⁴⁸ Issues of security, unlawful access, communication and interception of data, extortion in cyberspace, cyber fraud and the duties of a cyber-inspector are provided for in the ECTA.³⁴⁹

In its most common form, the use of electronic means includes electronic mail (e-mail), short message service (SMS), electronic data interchange (EDI), faxes, video calls and messenger services such as WhatsApp and Twitter.³⁵⁰ E-mail and SMS are valid means of contracting electronically.³⁵¹ An ordinary electronic signature as opposed to an advanced one was found to meet the requirements in terms of variation of a non-variation clause in a contract in the case of *Spring Forest Trading 599 CC v Wilberry (Pty) Ltd t/a Ecowash & another*.³⁵²

Electronic data interchange is generally used to transmit data and includes an ICD 10 code to a medical aid administrator.³⁵³ In *VRM V HPCSA*, the results of an HIV test were disclosed on a statement from a pathology laboratory that was sent to the main member of the medical aid.³⁵⁴

Thus, it is submitted that the use of EHR and electronic means is a valid means of electronic contracting. It is further asserted that the advanced electronic signature in the ECTA is valid when EHR are used.

4.3.8 The Protection of Personal Information Act³⁵⁵ (POPI)

The POPI gives effect to the constitutional right to privacy (s 14)³⁵⁶. While it generally prohibits the processing of certain personal information,³⁵⁷ certain sectors

³⁴⁷ *Snail op cit.*

³⁴⁸ See: *Swales op cit.* The writer submits that that the advanced signature in its current form should remain, especially when EHR are used and electronic healthcare contracts are entered into.

³⁴⁹ See: ECTA, section 81: Powers of Cyber inspectors; section 82: Powers to inspect, search and seize; section 84: Preservation of confidentiality. Section 86: Unauthorised access to, interception of or interference of data; section 87: Computer-related extortion, fraud and forgery.

³⁵⁰ Based on the writer's own experience in the medical and legal sectors.

³⁵¹ See: *Spring Forest Trading 599 CC v Wilberry (Pty) Ltd t/a Ecowash and another* 2015 (2) SA 118 (SCA). See also: *Jafta v Ezemvelo KZN Wildlife* 2008 (10) BLLR 954 (LC) 98. See further: Y Mupangavanh 'Electronic signatures and non-variation clauses in the modern digital world: The case of South Africa' (2016) 133(4) *SALJ* 853-873.

³⁵² See: *Spring Forest Trading supra.*

³⁵³ See: *VRM v HPCSA* TPD 1679/2002 (10 October 2003) unreported.

³⁵⁴ *VRM v HPCSA supra.*

³⁵⁵ Act 4 of 2013.

are exempt from this prohibition.³⁵⁸ Section 32 (1) and the prohibition on a data subject's health or sex life (s 26), does not apply to processing by:

- (a) '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;
- (b) insurance companies, medical schemes, medical scheme administrators and managed healthcare organisations, if such processing is necessary for:
 - (i) Assessing the risk to be insured by the insurance company or covered by the medical scheme and the data subject has not objected to the processing;
 - (ii) The performance of an insurance or medical scheme agreement; or
 - (iii) The enforcement of any contractual rights and obligations.'³⁵⁹

South African case law on this section of POPI is lacking and all sections have yet to come into effect. It is submitted that in the absence of case law, further processing of medical data has to conform to the provisions of statutory law discussed above³⁶⁰, the Medical Schemes Act³⁶¹ and the common law.

4.4 Security and authentication of electronic health records

Hacking of medical data has increased at the global level.³⁶² This raises important questions with regard to privacy, civil and criminal liability and the security of EHR systems.³⁶³ The healthcare sector has been identified as one of the most vulnerable.³⁶⁴ Financial sector cyber security safeguards have overcome similar challenges and are now a benchmark for online security standards.³⁶⁵ They offer useful security measures to consider when EHR are used, including:

³⁵⁶ The Constitution of the Republic of South Africa, 1996, section 14. See: POPI, The Preamble.

³⁵⁷ See: POPI Section 26 (a) prohibits the 'processing of special personal information concerning a person's health or sex life or biometric information of a data subject.'

³⁵⁸ See: POPI, section 32(1). See also: Behrtel *op cit* 4.

³⁵⁹ Ibid.

³⁶⁰ See: NHA, the Mental Health Care Act 17 of 2002, the Children's Act 38 of 2005, the CTOP, PAIA, CPA and the ETCA.

³⁶¹ Medical Schemes Act 131 of 1998.

³⁶² See: Gantt *op cit* 232-258.

³⁶³ Ibid.

³⁶⁴ R O'Harrow 'Health-care sector vulnerable to hackers, researchers say' *Washington Post* (December 25, 2012) available at https://www.washingtonpost.com/investigations/health-care-sector-vulnerable-to-hackers-researchers-say/2012/12/25/72933598-3e50-11e2-ae43-cf491b837f7b_story.html?utm_term=.7a0265d17f7a accessed 22 February 2017.

³⁶⁵ See: Gantt *op cit* 232-258.

- a) ‘Administrative safeguards;
- b) Physical safeguards;
- c) Technical safeguards;
- d) Organizational safeguards;
- e) Policy safeguards;
- f) Procedure safeguards; and
- g) Documentation safeguards.’³⁶⁶

It is submitted that administrative, physical and technical safeguards are generally beyond the control of MPs or a professional body such as the HPCSA. This is because EHR systems in SA are administered and controlled by the state, medical aid administrators and/or insurance companies. It is submitted that organizational, policy, procedural and documentation safety measures should be controlled by the HPCSA and / or MPs.

4.5 The Cybercrimes and Cybersecurity Bill³⁶⁷

The recently proposed Cybercrimes and Cybersecurity Bill³⁶⁸ provides for electronic service providers and financial institutions to report cybercrimes and assist in the investigation thereof. Provision is also made for additional security measures that are not provided for in other legislation.³⁶⁹ The Bill allows the executive to enter into security promotion agreements with foreign jurisdictions.³⁷⁰ It makes provision *inter alia*, for the following: cyber fraud; cyber forgery and uttering, and cyber extortion.³⁷¹

In addition to this Bill and statutory law, the HPCSA provides guidelines on health records.³⁷²

4.6 HPCSA guidelines on electronic health records

The HPCSA guidelines on health records are generally based on paper-based records and provide limited guidelines on the electronic processing of information.³⁷³ The

³⁶⁶ See: Gantt *op cit* 244-246.

³⁶⁷ Cybercrimes and Cybersecurity Bill of 2017 available at www.justice.gov.za/legislation/bills/CyberCrimesBill2017.pdf accessed 16 April 2017.

³⁶⁸ Ibid.

³⁶⁹ Ibid.

³⁷⁰ Ibid.

³⁷¹ Cybercrimes and Cybersecurity Bill of 2017, sections 8, 9 and 10.

³⁷² HPCSA *booklet 14* (2008).

³⁷³ See: HPCSA Booklet 9 (2016) *op cit*. See also: HPCSA Booklet 5 (2016) *op cit* 11.

guidelines recommend that MPs should be satisfied that security measures are adequate when electronic means are used.³⁷⁴ With the rapid evolution of technology and increased use of these devices in medical practice, there is a need to develop and recommend ethical guidelines for electronic resources.³⁷⁵

Telemedicine is a means of electronic communication in healthcare and is a variant of EHR.³⁷⁶ It is defined as:

‘The practice of medicine using electronic communications, information technology or other electronic means between a healthcare practitioner in one location and a healthcare practitioner in another location for the purpose of facilitating, improving and enhancing clinical, educational and scientific healthcare and research, particularly to the under-served areas in the Republic of South Africa.’³⁷⁷

It is submitted that the aim, objectives and purpose of telemedicine differ from EHR. However telemedicine encompasses aspects of EHR, when electronic means are used. EHR are more specific to the storage of records in an electronic form and the need to protect and preserve them. The HPCSA guidelines on telemedicine advocate for documented consent.³⁷⁸ Security measures such as data encryption, specialised authentication methods and password protection are equally important to telemedicine and the use of EHR.³⁷⁹

³⁷⁴ HPCSA Booklet 5 (2016) *op cit* 11.

³⁷⁵ See: C Jack and M Mars ‘Telemedicine a need for ethical and legal guidelines in South Africa’ (2008) 50(2) *South African Family Practise* 60-60(d).

³⁷⁶ HPCSA ‘Guidelines for good practice in the Healthcare professions’ General Ethical Guidelines for Good Practice in Telemedicine, Booklet 10 (2014) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%2010.pdf accessed 23 July 2017

³⁷⁷ *Ibid.*

³⁷⁸ HPCSA Booklet 10 (2014) *op cit* 8. The documentation regarding informed consent for telemedicine practice should include the following: (a) The patient’s name and address and the location or site of consultation; (b) The consulting practitioner’s name, practice address and number, and location; (c) The servicing practitioner’s or practitioner’s names, practice addresses and numbers, and location; (d) A brief explanation of telemedicine; (e) The types of transmissions consented to using telemedicine technologies (e.g. prescriptions, refills, appointment scheduling, patient education etc.). (f) Details of the security measures used in telemedicine technologies, such as encrypting data, password protected screen savers and data files, or other reliable authentication techniques. (g) Any material risks to confidentiality arising from the use of telemedicine technologies that may influence the patient’s decision to consent. The expected risks, possible benefits of and alternatives to telemedicine; The signature of the patient, the patient’s parent, the patient’s guardian or the patient’s caregiver - the relationship to the patient should be specified; The signature of the witness.

³⁷⁹ See: ETCA; POPI; NHA

While the HPCSA telemedicine guidelines do provide brief advice on the processing of electronic information, it is submitted that these recommendations are broad and do not adequately describe measures for the use of EHR.³⁸⁰

The guidelines:

- Advocate for appropriate security when electronic means is used to process medical data;
- Place an obligation on the medical professional to seek expert advice on the use of electronic devices for the processing of medical data;
- Place an obligation on the medical professional to secure the equipment used to transmit and receive electronic information; and
- State that a medical professional should be aware of the associated risks when using electronic means.³⁸¹

It is submitted that more specific measures are required within the ambit of these brief recommendations.³⁸² This calls for a comparative analysis of other countries that have more developed EHR systems.³⁸³

The HPCSA's ethical rules, statutory law and the common law are subordinate to the Constitution. What is of concern to MPs is the issue of liability when EHR are used.

4.7 Liability

In South Africa, no specific law relates to liability for EHR use. Liability for unlawful access and failure to protect health records applies equally to paper-based or electronic formats.³⁸⁴ Thus electronic and paper records are both governed by the NHA³⁸⁵ with added statutory obligations placed on EHR in terms of the ETCA³⁸⁶. In terms of the common law, liability for medical negligence, professional conduct liability and breach of contract are equally applicable in SA. Apart from the relevant statutes discussed above,³⁸⁷ the CPA introduced a system of strict liability. The MPS reviewed the HPCSA guidelines on confidentiality, consent and record-keeping and

³⁸⁰ See: HPCSA Booklet 10 (2014) *op cit* 9-14.

³⁸¹ *Ibid.*

³⁸² See: B Khubheka 'Ethical and legal perspectives on the medical practitioners use of social media by health professionals in South Africa' (2017) 107(5) *SAMJ* 386-389.

³⁸³ See further discussion in Chapter Five.

³⁸⁴ See: NHA, section 15:16 and 17. See also *Tshabalala-Msimang supra*.

³⁸⁵ National Health Act 61 of 2003.

³⁸⁶ Electronic Communications and Transactions Act 25 of 2002.

³⁸⁷ See: NHA; PAIA; CPA; ETCA; POPI;CTOP, The Children's Act and The Mental Health Care Act.

has conducted an analysis of the various statutory laws that aim to guide MPs to prevent unnecessary litigation.³⁸⁸

4.8 Conclusion

Electronic health records are in their infancy in SA. No specific legislation promotes their use or guides the medical profession on appropriate use thereof, nor are there guidelines for the use of EHR. Statutes that regulate paper-based health records, the common law, the *Tshabalala-Msimang* case, and security and authentication of EHR systems in foreign jurisdictions provide benchmarks to develop measures for use in SA. A comparative analysis of other jurisdictions is presented in chapter five.

³⁸⁸ Medical Protection Society ‘Medical Records in South Africa: An MPS Guide’ available at <http://www.medicalprotection.org/southafrica/advice-booklets/medical-records-in-south-africa-an-mps-guide> accessed 14 April 2017. MPS is a large medical practitioner insurer that has provided some basic guidelines (non-binding) for MPs to use or refer to when using an electronic health records.

CHAPTER FIVE

Comparative analysis of electronic health records guidelines

‘You also have the right to complain about healthcare services that either violate your rights to good health or breach ethical standards, to have your complaint investigated and to receive a full response thereafter.’³⁸⁹

5.1 Introduction

Comparative analysis of different jurisdictions in the medical and legal sector provides important lessons that can be used to design measures for the use of EHR and electronic means in SA. The Constitution³⁹⁰ allows for our courts to consider foreign law when interpreting the BOR. The laws that regulate EHR use in the US and UK are instructive, as well as the guidelines used in these countries. Therefore, these two countries laws and guidelines are used in this comparative analysis. Cybercrime and cyber-attacks have been more prevalent and more widely reported in these developed countries than in other countries.³⁹¹ This chapter thus focuses on the EHR guidelines in these countries.

5.2 United States of America guidelines

The HITECH Act of 2009 in the US provides for the establishment of a health information technology programme that requires certification, but is voluntary.³⁹² Certification is based on well-defined advantages such as interoperability and the ability to keep recorded data reliable and confidential.³⁹³

In response to the HITECH Act, the Food and Drug Administration (FDA) drafted guidelines for the use of EHR in clinical investigations.³⁹⁴ These are non-binding and provide recommendations on:

³⁸⁹ HPCSA ‘My Rights and Responsibilities’ available at <http://www.hpcs.co.za/Public/MyRights> accessed 23 July 2017.

³⁹⁰ The Constitution of the Republic of South Africa, 1996, section 39(1)(c).

³⁹¹ See: R O’Harrow *op cit*. See also: Brandom *op cit*.

³⁹² See: HITECH Act of 2009 (US). This Act requires the office of the national coordinator (ONC) to adopt the use of the broader term health IT in the ONC Health IT Certification Program that includes EHRs and other forms of health information technology that provides electronic data. See also: The ONC Health IT Certification Program available at <https://www.healthit.gov/policy-researchers-implementers/onc-health-it-certification-program> accessed 24 February 2017.

³⁹³ *Ibid* .

³⁹⁴ US Department of Health and Human Services Food and Drug Administration ‘Use of Electronic Health Record Data in Clinical Investigations’ (2016) available at <https://www.fda.gov/downloads/drugs/guidances/ucm501068.pdf> accessed 24 February 2017.

- ‘Deciding whether and how to use electronic health records as a source of data in clinical investigations;
- Using electronic health records that are interoperable with electronic systems supporting clinical investigations;
- Ensuring the quality and integrity of EHR data that is collected and used as electronic source data in clinical investigations.
- Ensuring that the use of EHR data collected and data used as electronic source data in clinical investigations meet FDA’s inspection, recordkeeping, and record retention requirements.’³⁹⁵

The FDA’s recommendations are based on an ‘attributable, legible, contemporaneous, original, and accurate’ (ALCOA) model that uses source data.³⁹⁶ The organization has accepted and provided recommendations for sponsors that are non-ONC certified. In these circumstances, confidentiality, integrity, reliability of data and internal security measures are important factors that sponsors need to consider when EHR systems are used to ensure that:

- ‘Access to electronic systems is limited to authorized users;
- Authors of records are identifiable;
- Audit trails are available to track changes to data;
- Records are available and retained for FDA inspection for as long as the records are required by applicable regulations.’³⁹⁷

The FDA further reinforces the importance of informed consent, privacy, record preservation and security measures.

Despite legislation such as the HITECH Act and the FDA guidelines, American physicians are still challenged by the lack of an inter-operable public-private EHR system.³⁹⁸ The UK’s legislation and guidelines on EHR use differ from those used in the US.

³⁹⁵ FDA *op cit* 1-2.

³⁹⁶ FDA *op cit* 1-2.

³⁹⁷ FDA *op cit* 6.

³⁹⁸ American Medical Association ‘AMA Continues Efforts to Improve Electronic Health Records’ (2016) available at <https://www.ama-assn.org/content/american-medical-association-continues-efforts-improve-electronic-health-records> accessed 24 February 2017.

5.3 United Kingdom guidelines

The UK is divided into England, Wales, Scotland and Northern Ireland, for purposes of this discussion on the use of EHR.³⁹⁹ England and the other three countries lack specific legislation on such records.⁴⁰⁰ Medical records (paper and electronic) formats are referred to in legislation, which regulates the type of IT systems that general medical practitioners (GPs) use in their practice, as well as their use of e-prescriptions.⁴⁰¹

The National Health Service (NHS) in England uses a ‘Summary Care Record’ (SCR) that stores data on a central NHS computer, which can be accessed nationally by authorised staff.⁴⁰² Important aspects of the SCR system are as follows:

- The SCR system is only used by GPs;
- An extract or subset of the SCR record involving core information is accessible for emergencies and after hours consultations;
- Sensitive data such as HIV/AIDS status, sexually-transmitted diseases and termination of pregnancy data, is not available in the SCR record;
- GPs have been advised to retain EHR for medico-legal evidence. This is despite the Data Protection Act⁴⁰³ (UK) which states that personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes; and
- A licence standard and approval by the NHS is required for the hosting of EHR.⁴⁰⁴

It is submitted that the NHS measures such as a SCR, and limited access to sensitive data such as a person’s HIV status and termination of pregnancy data should be incorporated into South African guidelines. In addition to these EHR systems, professional bodies regulate health records and the use of electronic communication.

³⁹⁹ See: C George ‘Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services’ (2014) available at http://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_united_kingdom_en.pdf accessed 25 February 2017. It is noted, each of the home countries use separate EHR systems that are not interoperable.

⁴⁰⁰ George *op cit* 329.

⁴⁰¹ Ibid.

⁴⁰² George *op cit*. It is noted that as at 2014, the Summary Care Record (SCR) had created over 34 million electronic summary records.

⁴⁰³ Data Protection Act 1998 (UK), Principle 5.

⁴⁰⁴ George *op cit* 329.

The General Medical Council (UK) provides guidelines on the use of social media for general record-keeping.⁴⁰⁵ These state that social media consultations should apply similar principles to those established for face-to-face consultations.⁴⁰⁶ Other professional bodies such as the British Psychological Society (UK) have recommended guidelines for the use of EHR.⁴⁰⁷ The Society recommends a secure, access-controlled electronic environment for EHR as the preferred choice for storage and preservation of records, over paper-based record systems.⁴⁰⁸ However, it makes provision for exceptions where electronic sharing of patients' information is not in the best interests of the patient, such as their HIV status; sexually-transmitted disease diagnosis and mental illnesses diagnosis.⁴⁰⁹

5.4 Conclusion

In the US, the FDA draft guidelines such as an ALCOA⁴¹⁰, and factors such as limited access and an identifiable author are important measures for EHR and electronic means use. In the UK, where no legislation exists for the use of EHR, the SCR system provides some core aspects, such as limitations for use in emergency situations and the protection of sensitive data. Incorporation of these core aspects from both jurisdictions is important for EHR use in SA.⁴¹¹

⁴⁰⁵ Social media is now an efficient and established means of electronic communication in the UK. See: General Medical Council 'Good Medical Practice' (2013) note 19-21 available at http://www.gmc-uk.org/static/documents/content/GMP_.pdf accessed 24 February 2017. See also: General Medical Council *op cit* note 4-5. 'Social media describes web-based applications that allow people to create and exchange content. In this guidance we use the term to include blogs and microblogs (such as Twitter), internet forums (such as doctors.net), content communities (such as YouTube and Flickr), and social networking sites (such as Facebook and LinkedIn)'.

⁴⁰⁶ See: General Medical Council *op cit* 105.

⁴⁰⁷ British Psychological Society 'Guidelines on the use of electronic health records' (2011) available at http://www.bps.org.uk/sites/default/files/documents/electronic_health_records_final.pdf accessed 24 February 2017.

⁴⁰⁸ British Psychological Society *op cit* note 5.

⁴⁰⁹ *Ibid.*

⁴¹⁰ ALCOA model: attributable, legible, contemporaneous, original.

⁴¹¹ cf Kubheka *op cit* 388.

CHAPTER SIX

Conclusion

'Every citizen has the right to participate in the development of health policies, as well as the right to participate in decision-making on matters affecting one's own health.'⁴¹²

6.1 Introduction

The aim of this study was to critically evaluate the measures used when EHR and electronic means are used in SA. The core issue is that private, confidential information is being transmitted electronically. Unlawful disclosure of health records impairs a patient's right to dignity and privacy. The study's objective was to formulate a set of guidelines that MPs can implement. The evaluation of the measures involved a review of South African and foreign legislation, case law and various guidelines recommended by the HPCSA.⁴¹³ A comparative analysis was conducted of the measures recommended in the US and UK. The research sub-questions provided reference points to answer the main research question.

6.2 Type of contract and exemption clauses

6.2.1 Type of contract required

It is recommended that a written contract be the acceptable standard in an era where digitalization of records has changed the MP-patient relationship.⁴¹⁴

6.2.2 Exemption clauses in the contract

The contract should not contain unjust, unfair and unreasonable terms, when:

- a) An MP and patient contract for the use of an EHR system; and
- b) The terms of the contract are for the disclosure of information to another MP, insurance company or medical aid administrator.⁴¹⁵

It should be noted that academic writers have called into question the future validity of the *Afrox Health Care* case in light of the introduction of the CPA⁴¹⁶, amongst other reasons.⁴¹⁷

⁴¹² Department of Health: 'National Patient's Rights Charter' available at [http://www.justice.gov.za/VC/docs/policy/Patient Rights Charter.pdf](http://www.justice.gov.za/VC/docs/policy/Patient%20Rights%20Charter.pdf) accessed 24 March 2017.

⁴¹³ See: HPCSA Booklet 1-15 (2016) *op cit*.

⁴¹⁴ See: Wright *op cit* 1. Further: a written contract can serve as evidence in the event of a dispute on the terms were agreed on by the parties.

⁴¹⁵ See: *Afrox Health Care* (SCA) *supra*. See also: Naude & Lubbe *op cit* 441-446. See further: Rowe and Moodley *op cit* 1-9. See further: McQuoid-Mason (2012: *SAJBL*) *op cit* 65-68.

⁴¹⁶ Consumer Protection Act 68 of 2008.

⁴¹⁷ See: The CPA. See also: Naude & G Lubbe *op cit* 44-446. See further: Rowe & Moodley *op cit* 1-9.

6.3 Informed consent and electronic health records

6.3.1 Standard of care for informed consent

The informed consent codified in the NHA⁴¹⁸ differs from consent to disclose health records in an EHR system or via electronic means.⁴¹⁹ *Castell v de Greef* is the guiding law in SA.⁴²⁰ Thus, a separate clause on informed consent, EHR and electronic means use is required in the MP-patient contract.⁴²¹ The *Castell* principles provide a checklist for determining whether informed consent was validly obtained.

The patient must know what the treatment or procedure is, what its material risks are, understand these risks and consent to the entire process for consent to be valid.⁴²²

The consent must be comprehensive and disclosure should involve the following:

- a) That disclosure may need to be made to other MPs involved in the care, treatment or rehabilitation of the patient.⁴²³
- b) Medical data that is highly sensitive must be transmitted via electronic means that are less disposed to interception and hacking.
- c) Measures that prevent or diminish the risks of hacking and interception of data must be disclosed to the patient.⁴²⁴
- d) The identity of the third party that is in control of the EHR system must be disclosed to the patient.⁴²⁵
- e) Security measures, encryption and authentication processes that are in place must be disclosed to the patient.⁴²⁶
- f) Whether an opt-in or opt-out EHR system is being used.⁴²⁷ The patients must consent to the system used, as per provisions in the NHA.⁴²⁸

6.3.2 Length of informed consent

⁴¹⁸ National Health Act 61 of 2003.

⁴¹⁹ See: Chapter two: 2.2.3.

⁴²⁰ See: Chapter two: 2.2.3. See also *Castell* supra. See further: Thomas *op cit* 196.

⁴²¹ See: Paragraph question one answered above.

⁴²² See: Chapter two: 2.4. See also: McQuoid-Mason SAHeart *op cit* 249.

⁴²³ See: Chapter two: 2.2.2. See also: *Jansen Van Vuuren v Kruger* supra. Disclosure of a patient's HIV status to a dentist by a medical practitioner on a golf course was deemed not to be in the scope of care and treatment of the patient.

⁴²⁴ See: O'Harrow *Washington Post* (December 25, 2012) *op cit*. See also: Grant *op cit*.

⁴²⁵ See: Chapter three: 3.2.2. See also: Hall *op cit* 642.

⁴²⁶ See: Chapter three: 3.5. See also: Grant *op cit* 232. See further: Paul *op cit* and Pagilery *op cit*.

⁴²⁷ See: Riodan et al *op cit* 237-247. See also: Cahana and Hurst *op cit* 446-451.

⁴²⁸ See: NHA, section 7(1) & 7(2). See also: Chapter four 4.3.1.

- a) EHR system data should remain on the system from birth until death, subject to legislation such as POPI and PAIA compliance.⁴²⁹
- b) An SCR should be used for emergency care, provided that the patient has control over what information is on the system.⁴³⁰

6.3.3 Disclosure and access to electronic health records

- a) Disclosure of EHR or data via electronic means from one MP to another must be within the scope of their duties as an MP, advancing care, rehabilitation and treatment of the patient.⁴³¹
- b) Insurance companies require accurate and current medical information. This must be correctly disclosed on an EHR system with access limited to the insurer and the patient.⁴³²
- c) Medical aid administrators require an ICD 10 code to process claims. Written consent is recommended for disclosure of ICD 10 codes to medical aid administrators, insurance companies and other MPs on an EHR system or via electronic means such as EDI.⁴³³
- d) EHR must be disclosed for a legitimate purpose, within the scope of medical practice and if in the interests of the patient.⁴³⁴
- e) Administrative, support staff at:
 - i. Medical practices;
 - ii. Clinics;
 - iii. Hospitals;
 - iv. Medical aid offices; and
 - v. Information technology service offices
 are allowed access to EHR systems, this data can be further processed, provided the patients are informed about the use of the data.⁴³⁵

⁴²⁹ See: Chapter three: 3.3 Electronic health records versus paper-based records. See also: Chapter four: 4.9. The Protection of Personal Information Act (POPI). See further: Chapter four: 4.6 The Promotion of Access to Information Act (PAIA).

⁴³⁰ See: Chapter five: 5.3. United Kingdom guidelines. See also: George *op cit* 31. The writer refers to SCR use in the emergency clinical setting, where SCR can save lives. Information detailing chronic medication and allergies and past relevant treatment is included herein.

⁴³¹ See: Chapter two: 2.2.2. Confidentiality in Medical Practice. See also: *Jansen Van Vuuren v Kruger*.

⁴³² See: *Hague v Williams* supra 349.

⁴³³ See: Chapter four 4.8. See also: *VRM v HPCSA* supra. This case discussed the importance of consent and confidentiality in healthcare, when sensitive test results are disclosed to third parties such as medical aid administrators. See also: HPCSA Booklet 4 (2016) *op cit* 14. Note that ICD 10 disclosure and consent is included in these updated 2016 guidelines.

⁴³⁴ See: Chapter four: 4.3 Statutory Law: 4.3.1 The National Health Act. See also: NHA, section 15(1).

6.4 Steps for electronic health records use with electronic means

Safeguard measures are required at two levels, within an organization⁴³⁶ and outside an organization.

Within an organization, it is imperative to incorporate policy, procedural and documentation safeguard measures into daily medical practice.⁴³⁷

Outside the organization, the following security measures should be used for the disclosure of EHR systems and when electronic means are used:

- (a) An ALCOA⁴³⁸ model should be used when electronic transmission is made to service providers.⁴³⁹
- (b) Access should be granted to identifiable users only and amendments of records must be tracked.⁴⁴⁰
- (c) An SCR⁴⁴¹ should be available for emergency care.⁴⁴²
- (d) Sensitive data such as HIV results, sexually-transmitted diseases, termination of pregnancy and mental illness on an EHR system must be limited and not within the patients control.⁴⁴³
- (e) In the case of insurance companies, only the requested and consented to information should be placed on the EHR system.⁴⁴⁴
- (f) Medical aid administrators require an ICD 10 code to process medical aid claims and informed consent must be obtained for disclosure of such information on an EHR system.⁴⁴⁵
- (g) Children over the age of 12, with sufficient maturity, may consent independently to disclosure on an EHR system.⁴⁴⁶

⁴³⁵ See: Chapter Four 4.9 The Protection of Personal Information Act. See also: The POPI, section 32(1). See further: Behrtel *op cit* 4.

⁴³⁶ Organisation herein refers to medical practices, clinics, hospitals, medical aid administrators and information support organisations.

⁴³⁷ See: Chapter four 4.10. See also: Gantt *op cit* 247.

⁴³⁸ ALCOA: 'attributable, legible, contemporaneous, original, and accurate', recommended by FDA.

⁴³⁹ See: Chapter five: 5.2. United States of America. See also: FDA *op cit* 1-2.

⁴⁴⁰ See: Ibid.

⁴⁴¹ SCR: Summary care record.

⁴⁴² See: George *op cit*.

⁴⁴³ See: Chapter five: 5.3. United Kingdom. See also: British Psychological Society guidelines (2011) *op cit* note 7. Further: a pin coded, patient access control system is advocated.

⁴⁴⁴ See: Chapter two: 2.2.2. See also: *Hague v Williams* supra 349. See also: This data must only be accessible on demand on a need to know basis by MPs

⁴⁴⁵ See: Chapter four: 4.8. See also *VRM v HPCSA* supra.

⁴⁴⁶ See: Chapter four: 4.4 The Children's Act. See also: Children's Act 38 of 2005, section 129(2) - 29(3) and section 134(3).

(h) Information on the use of contraceptives by children must be kept on a secure, access controlled EHR system.

(f) An *opt-in* informed consent EHR model should be used, which requires consent by the patient.⁴⁴⁷

6.5 Ethical considerations for EHR and the use of electronic means

- a) Face-to-face consultation ethical principles apply when electronic means such as social media⁴⁴⁸ are used to transmit health records.⁴⁴⁹
- b) In exceptional circumstances, autonomy may be sacrificed (eg. in an emergency situation) and a SCR can be used in such circumstances.⁴⁵⁰
- c) A collaborative partnership model should be used to implement an EHR system and the advancement of newer electronic technology in medical practice;⁴⁵¹
- d) Favourable risk-benefit ratios and added social value benefits should be considered; and
- e) Justice, equity and access are some of the broader ethical principles that should be considered for the use of electronic means in clinical medical practice.⁴⁵²

6.6 Conclusion

Globally, EHR systems and the use of electronic means are developing at an exponential rate. This study therefore is of practical importance for medical practice. However, in advocating such guidelines, cognizance should be taken of the many unresolved issues such as property rights, and whether a different standard should be applied for informed consent when EHR or electronic means are used. It is submitted that these issues provide a firm foundation for further research in this area.

⁴⁴⁷ See: Chapter two paragraph 2.2.3: The doctrine of informed consent in medical practice. See also: Riordan et al *op cit* 237-247.

⁴⁴⁸ Social media include Whatsapp; Twitter, Facebook and newer, emerging social media applications.

⁴⁴⁹ See: Chapter five: 5.3. United Kingdom. See also: GMC *op cit* note 19-21. See further: GMC *op cit* note 4-5. See also: Khubheka *op cit* 386-389.

⁴⁵⁰ See: Chapter five 5.3. United Kingdom. See also: George *op cit* 12-24. Further noted: That the electronic health record system in use by a private medical aid administrator in South Africa equates to a summary care record (SCR) system with pertinent important medical data that can aid a practitioner in an emergency situation.

⁴⁵¹ The writer cautions against the use of certain electronic means that are not equivalent to a face-face consultation, such as when the precise identity of the recipient of communication is not known to the sender.

⁴⁵² See: GMC (2013) *op cit* note 19-21. See also: Emanuel et al *op cit* 930-937.

BIBLIOGRAPHY

BOOKS

Beauchamp TL & Childress JF *Principles of Biomedical Ethics* 6th ed New York: Oxford University Press (2008).

Carstens P & Pearmain D *Foundational Principles of South African Medical Law* 1 ed Durban: Lexis Nexis (2007).

Claassen NJB & Verschoor *Medical Negligence in South Africa* Pretoria: Digma Publications (Pty) Ltd (1992).

Christie RH & Bradfield GB *Christie's: The Law of Contract in South Africa* 6th ed Cape Town: Lexis Nexis (2011).

Currie I & De Waal J *The Bill of Rights Handbook* 5 ed Cape Town: Juta and Company Ltd (2005).

Dada MA & McQuoid-Mason DJ *Introduction to Medico-Legal Practice* 1 ed Durban: Butterworths (2001).

Dhai A & McQuoid-Mason DJ *Bioethics, Human Rights and Health Law: Principles and Practice* 1 ed Cape Town: Juta (2011).

Giesen D *International Medical Malpractice Law* 1 ed (1988).

Glover JD *Causing Death and Saving Lives* New York: Penguin Books (1977).

Kerr AJ *The Principles of the Law of Contract* 5 ed (1998).

Lawson R *Exclusion Clauses and Unfair Contract Terms* 10 ed (2011).

McQuoid-Mason DJ & Dada MA *A-Z Medical Law* 1 ed Cape Town: Juta (2011).

Moodley K *Medical Ethics, Law and Human Rights – A South African Perspective*
Cape Town: Juta (2011).

Mostert H Pope A Badenhorst P Freedman W Pienaar J & Van Wyk J *The Principles of the law of Property in South Africa* Durban: Oxford (2010) .

Neethling J Potgieter JM & Knobel JC *Neethling-Potgieter-Visser: Law of Delict* 6th
ed Cape Town: Lexis Nexis (2010).

Neethling J Potgieter JM & Visser PJ *Neethling's Law of Personality* 1 ed Cape
Town: Lexis Nexis (2005).

Sharrock R *Business Transactions Law* 8th ed Cape Town: Juta (2012).

Strauss SA *Doctor, Patient and the Law* 3 ed Cape Town: Van Schaik (1991).

JOURNAL ARTICLES

Albertus L 'Has the Balance Been Struck? The Decision in *Johncom Media Investments Limited V M* 2009 4 SA 7 (CC)' (2011) 14(1) *Potchefstroom Electronic Law Journal* 216-234.

Behrtel U 'Anonymous Patient Profiling: Is this ethical and can this data be sold?'(2016) 2(1) *Treatment Tutor* 4.

Blake V 'When is a Patient-Physician Relationship Established' (2012) 14(5) *Virtual Mentor* 403-406.

Brand FDJ 'The Role of Good Faith, Equity and Fairness in the South African Law of Contract: The Influence of the Common Law and the Constitution' (2009) 126(1) *South African Law Journal* 71-90.

Britz R & le Roux-Kemp A 'Voluntary informed consent and good clinical practice for clinical research in South Africa : Ethical and legal perspective' (2012) 102(9) *SAMJ* 746-748.

Burchell J 'The legal protection of privacy in South Africa: A transplantable hybrid' (2009) 13(1) *Electronic Journal of Comparative Law* 1-26.

Cahana A & Hurst SA 'Voluntary informed consent in research and clinical care: an update' (2008) 8(6) *Pain Practice* 446-451.

Carstens PA 'Access to medical records without consent of the patient and the publication thereof in the public domain: Issues of privacy, dignity, freedom of expression and the public interest. Tshabalala-Msimang and Medi-Clinic Ltd v Makhanya 2008 3 BCLR 338 (W)' (2008) 29(2) *Obiter* 291-301.

de Klerk A 'The right of patients to have access to their medical records: the position in South African law' (1993) 12 *Medical Law* 77-83.

Emanuel EJ Wendler D Killen J & Grady C 'What makes clinical research in developing countries ethical? The benchmarks of ethical research' (2004) 189(5) *Journal of Infectious Disease* 794-795.

Gillon R 'Ethics Needs Principles – Four Can Encompass the Rest – and Respect for Autonomy Should be First Among Equals' (2003) 29(5) *Journal of Medical Ethics* 307-312.

Gantt G 'Hacking health care: Authenticating security in the age of meaningful use' (2014) 27(232) *Journal of Law and Health* 232-258.

Hall MA 'Property, privacy, and the pursuit of interconnected electronic medical records' (2010) 95(2) *Iowa Law Review* 631-664.

Harris J 'Consent and End of Life Decisions' (2003) 29(1) *Journal of Medical Ethics* 10-15.

Jack C & Mars M 'Telemedicine a need for ethical and legal guidelines in South Africa' (2008) 50(2) *South African Family Practise* 60-60d.

Kluyts H 'Can information technology improve my ambulatory practice' (2015) 2(1) *South African Journal of Anaesthesia and Analgesia* 59-61.

Khubheka B 'Ethical and legal perspectives on the medical practitioners use of social media by health professionals in South Africa' (2017) 107(5) *SAMJ* 386-389.

Mangalmurti SS Murtagh L & Mello MM 'Medical Malpractice Liability in the age of electronic health records' (2010) 363(21) *The New England Journal of Medicine* 246-254.

Mayosi BM & Benatar SR 'Health and Health Care in South Africa – 20 Years after Mandela' (2014) 371(14) *New England Journal of Medicine* 1344-1353.

McQuoid-Mason DJ 'Disclosing the health status of public figures: Privacy versus public interest – when may doctors make public disclosure?' (2007) 97(10) *SAMJ* 920-923.

McQuoid-Mason DJ 'Hospital exclusion clauses limiting liability for medical malpractice resulting in death or physical or psychological injury: What is the effect of the Consumer Protection Act?' (2012) 5(2) *SAJBL* 65.

McQuoid-Mason DJ 'Medical records and access thereto' (1996) 15(3) *Medical Law* 499-509.

McQuoid-Mason DJ 'Michael Jackson and the limits of patient autonomy' (2012) 5(1) *SAJBL* 11-14.

DJ McQuoid-Mason 'Invasion of Potency?' (1973) 90(23) *SALJ* 29.

- McQuoid-Mason DJ 'Termination of pregnancy and children: Consent and confidentiality issues' (2010) 100(1) *SAMJ* 213-214.
- McQuoid- Mason DJ 'The effect of the new Children's Act on consent to HIV testing and access to contraceptives by children' (2007) 97(12) *SAMJ* 1252-1253.
- McQuoid-Mason DJ 'What constitutes medical negligence? A current perspective on negligence versus malpractice' (2010) 7(4) *SAHeart* 248-251.
- Moreno J 'The Triumph of Autonomy in Bioethics and Commercialism in American Healthcare.' (2007) 16(4) *Cambridge Quarterly of Healthcare Ethics* 415-419.
- Mupangavanhu Y 'Electronic signatures and non-variation clauses in the modern digital world: The case of South Africa' (2016) 133(4) *SALJ* 853-873.
- Naidoo S 'Ethics corner: Patient access to records' (2013) 68(1) *SADJ* 36-37.
- Naude T & Lubbe G 'Exemption Clause – A Rethink Occasioned by the *Afrox Healthcare BPK v Strydom*' (2005) 5(1) *The South African Law Journal* 441-446.
- Oosthuizen WT & Carstens PA 'Medical malpractice: The extent consequences and causes of the problem' (2015) 78 *THRHR* 269-284.
- Oosthuizen WT & Carstens PA 'Re-evaluating medical malpractice: A patient-safety approach' (2015) 78 *THRHR* 380-396.
- Pasterneck ES 'HIPPA in the age of electronic health records' (2010) 41(3) *Rutgers Law Journal* 817- 864.
- Pepper MS & Slabbert MN 'Is South Africa on the verge of a medical malpractice litigation storm' (2011) 4(1) *SAJBL* 29-35.
- Pienaar GJ 'Registration of informal Land use rights in South Africa: Giving Teeth to (toothless?) paper tigers' (2000) 3 *TSAR* 442-468.

Riordan F Papoutsis C Reed JE Marston C Bell D & Majeed A 'Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK' (2015) 84(4) *International Journal of Medical Informatics* 237-247.

Rowe K & Moodley K 'Patients are consumers in healthcare in South Africa: the ethical and legal implications' (2013) 14(15) *BMC Medical Ethics* 1-9.

Schachter O 'Human Dignity as a Normative Concept' (1983) 77(4) *American Journal of International Law* 848-853.

Stearns PV 'Access to and cost of reproduction of patient medical records: a comparison of state laws' (2000) 21(1) *Journal of legal medicine* 79-105.

Sitting DF & Singh H 'Legal, Ethical, and Financial Dilemmas in Electronic Health Record Adoption and Use' (2011) 127(4) *Pediatrics* e1042-1047.

Stausberg J Koch D Ingenerf J & Betzler M 'Comparing Paper-based with Electronic Patient Records: Lessons Learned during a Study on Diagnosis and Procedure Codes' (2003) 10(5) *Journal of the American Medical Informatics* 470-477.

Strode A Slack C & Essack Z 'Child consent in South Africa: Implications for researchers, service providers and policy makers' (2011) 101(9) *SAMJ* 604-606.

Swales L 'The regulation of electronic signatures: Time for review and amendment' (2015) 15(2) *SALJ* 259.

Kumar NK 'Informed consent: Past and present' (2013) 4(1) *Perspective in clinical Research* 21-25.

Terry NP & Francis LP 'Ensuring the privacy and confidentiality of electronic health records' (2007) 861(2) *University of Illinois Law Review* 681-736.

Thomas R 'Where to from *Castell v De Greef*? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure' (2007) 124(1) *SALJ* 188-215.

Varelius J 'The value of autonomy in medical ethics' (2006) 9(3) *Medicine Health Care Philosophy* 377-388.

Webster PC 'CMA takes on electronic medical records' (2015) 1187(15) *Canadian Medical Association Journal* E440.

Were MC & Meslin EM 'Ethics of implementing electronic health records in developing countries' (2011) *AMIA Annual Symposium Proceedings Archive* 1499-1505.

Wright A 'You, Me and the Computer Makes Three: Navigating the Doctor-Patient Relationship in the Age of Electronic Health Records' (2015) 30(1) *Journal of General Internal Medicine* 1-2.

Venter Z 'Girl (6) to have brain operation despite dad's refusal' *Pretoria News* (30/10/2006).

Venter Z 'Tug-of-war over teen stricken by cancer' *Pretoria News* (26/01/2007).

THESES

Alhaqbani BS *Privacy and Trust Management for Electronic Health Records* unpublished Doctor of Philosophy Dissertation Queensland University of Technology Brisbane Australia (2010).

Kok C *The Effect of the Consumer Protection Act on Exemption Clauses in Standardised contracts* unpublished LLM Thesis University of Pretoria (2010).

Lerm H A *Critical Analysis of Exclusionary Clauses in Medical Contracts* unpublished LLD Thesis University of Pretoria (2008).

Mahlaola TB *Compliance of health professionals with patient confidentiality when PACS and RIS* unpublished Magaster Technologiae in Radiology Thesis University of Johannesburg (2013).

Ramkaran T A *Critical Analysis of Exclusionary Clauses in Medical Contracts* unpublished LLM Thesis University of KwaZulu-Natal (2013).

Ross A *The law of data (privacy) protection: a comparative and theoretical study* unpublished LLD Thesis University of South Africa (2003).

Scharf GM *The medico-legal pitfalls of the medical expert witness* unpublished LLM Thesis University of South Africa (2014).

Singh R *Criminal liability for HIV/AIDS infection: Comparative study* unpublished LLM Thesis Nelson Mandela Metropolitan University (2012).

Vervey H *Wish-fulfilling medicine: legal and bioethical perspectives with reference with reference to the practice of cosmetic surgery* unpublished Magaster Legum Thesis University of Pretoria (2013).

CASES

South Africa

Administrator, Natal v Edouard 1990 (3) SA 581 (A).

Afrox Health Care Limited v Strydom 2002 (6) SA 21 (SCA).

Bannatyne v Bannatyne 2003 (2) SA 363 (CC).

Barkhuizen v Napier 2007 (5) SA 323 (CC).

Botha v Botha 1972 (2) SA 559 (N).

Brisley v Drotsky 2002 (4) SA 1 (SCA).

Broude v McIntosh 1998 (3) SA 60 (SCA).

Burger v Medi-Clinic Unreported judgement Witwatersrand Local Division (1999).

C v Department of Health and Social Development, Gauteng 2012 (2) SA 208 (CC).

C v Minister of Correctional Services 1996 (4) SA 292 (T).

Carmichele v Minister of Safety and Security 2001 (4) SA 938 (CC).

Castell v de Greef 1994 (4) SA 408 (C).

Christian Lawyers' Association v Minister of Health 2004 (10) BCLR 1086 (T).

Dawood v Minister of Home Affairs 2000 (3) SA 936 (CC).

Dikoko v Mokhatla 2006 (6) SA 235 (CC).

Director of Public Prosecutions: Cape of Good Hope v Bathgate 2000 (2) SA 535 (C).

Durban's Water Wonderland (Pty) Ltd v Botha 1999 (1) SA 982 (SCA).

Dutch Reformed Church v Rayan Sooknunan 2012 (6) SA 201 (GSJ).

Esterhuizen v Administrator, Transvaal 1957 (3) SA 710 (T).

George v Fairmead (Pty) Ltd 1958 (2) SA 465 (A).

Glen v Glen 1979 (2) SA 1113 (T).

Glatthaar v Hussan 1912 TPD 322.

Greeff v Protection 4U h/a Protect International 2012 (6) SA 392 (GNP).

Hay v B 2003 (3) SA 492 (W).

Hoffmann v South African Airways 2000 (11) BCLR 1211 (CC); 2001 (1) SA (CC)
Investigating Directorate: Serious Economic Offences v Hyundai Motor Distributors (Pty) Ltd: In re Hyundai Motor Distributors (Pty) Ltd v Smit NO 2001 (1) SA 545 (CC).

Isparta v Richter 2013 (6) SA 4529 (GP).

Jafta v Ezemvelo KZN Wildlife 2008 (10) BLLR 954 (LC).

Jansen van Vuuren v Kruger 1993 (4) SA 842 (A).

Johncom Media Investments v M 2009 (4) SA 7 (CC).

Ketler Investments CC t/a Ketler Presentations v Internet Service Providers' Association 2014 (2) SA 569 (GJ).

Kidson v SA Associated Newspapers Ltd 1957 (3) SA 461 (W).

Le Roux v Dey 2011 (3) SA 274 (CC).

Louwrens v Oldwage 2006 (2) SA 161 (SCA).

National Coalition for Gay and Lesbian Equality v Minister of Justice 1999 (1) SA 6 (CC).

Nyathi v MEC for the Department of Health, Gauteng 2008 (5) SA 94 (CC).

MEC for Health, Mpumalanga v M-Net 2002 (6) SA 714 (T).

McDonald v Wroe 2006 (3) All SA 565 (C).

NM and Others v Smith and Other 2007 (5) SA 250 (CC).

Mistry v Interim Medical and Dental Council of South Africa 1998 (4) SA 1127 (CC).

O'Keeffe v Argus Printing and Publishing Co Ltd 1954 (3) SA 244 (C).

Tshabalala-Msimang and another v Makhanya 2008 (6) SA 102 (W).

Parkes v Parkes 1916 CPD 702.

Richter and another v Estate Hammann 1967 (3) SA 226 (C).

S v Dodo 2001 (3) SA 382 (CC).

S v M 2008 (3) SA 232 (CC).

S v Makwanyane 1995 (3) SA 391 (CC).

SAR & H v National Bank of SA Ltd 1924 AD 704.

Stoffberg v Elliot 1923 CPD 148.

South African Forestry Ltd v York Timbers Ltd 2005 (3) SA 323 (SCA).

Spring Forest Trading 599 CC v Wilberry (Pty) Ltd t/a Ecowash & another 2015 (2) SA 118 (SCA).

Tothill v Forster 1925 TPD 857.

Willis J in Heroldt v Wills 2013 (2) SA 530 (GSJ).

Van Wyk v Lewis 1924 AD 438.

VRM v HPCSA TPD 1679/2002 (10 October 2003) unreported.

Australia

Rogers v Whitaker [1992] 109 ALR 625.

United Kingdom

Copland v United Kingdom [2007] ECHR 253.

X v Y 1988 ALL ER 648 (QBD).

United States of America

Childs v Weis 440 SW2d 104 (Ct Civ App Tx 1969).

Estate of Finkle 395 N.Y.S 2d (N.Y. 1977).

Hague v Williams 1962 (181) Atlantic Reporter 2d 345 at 349.

Hurley v Eddingfield 59 NE 1058 (Ind 1901).

Mead v Adler 220 P3d 118 (Or 2009).

Ricks v Budge 64 P2d 208 (Utah 1937).

Salgo v Leland Stanford Junior University Board of Trustees 317 P 2d 170 (Cal 1957).

Schloendorff v Society of New York Hospitals 105 N.E. 92 (N.Y. 1914).

Tarasoff v Regents of the University of California (1976) Cal SCt, 17 Cal Rep 3rd series 425.

Namibia

N v Minister of Defence (2000) ILJ 999 (Labour Court of Namibia).

POLICY AND ETHICAL GUIDELINES

The Cybercrimes and Cybersecurity Bill of 2017

Section 8

Section 9

Section 10

The Health Professions Council of South Africa Guidelines on Ethical rules
Ethical rules, regulations and policy guidelines (*Booklet 1-15*)

ACTS

South Africa

Children's Act No 38 of 2005

Section 129(2)

Section 129(3)

Section 130

Section 133(1)

Section 134(3)

Choice on Termination of Pregnancy Act 92 of 1996

Section 5(2)

Section 5(3)

Section 7(1) – 7(5)

Section 10(1)

Constitution of the Republic of South Africa, 1996

Section 10
Section 12 (2) (c)
Section 14
Section 14(d)
Section 16(1)(a)

Consumer Protection Act No 68 of 2008

Section 1
Section 48
Section 49
Section 52(3)
Section 52(4)
Section 61(3)

Criminal Procedure Act 51 of 1977

Section 276(1)(i)

Electronic Communications and Transactions Act No 25 of 2002

Section 1
Section 2(1) (a)
Section 2(1) (f)
Section 81
Section 82
Section 84
Section 86
Section 87

National Health Act No 61 of 2003

Section 6

Section 7

Section 7(1)

Section 7(2)

Section 8

Section 9

Section 14(1)

Section 14(2)

Section 15

Section 16

Section 17

Medical Schemes Act No 131 of 1998

Mental Health Care Act No 17 of 2002

Section 13(1)

Section 13(2)

Occupational Health and Safety Act 85 of 1993

Prescription Act 68 of 1969

Promotion of Access to Information Act 2 of 2000

Section 30(3)(a)

Section 60(1)(b)

Section 60(2)(a).

Protection of Personal Information Act 4 of 2013

Preamble

Section 26 (a)

Section 32(1)

Promotion of Equality and Prevention of Unfair Discrimination Act No 4 of 2000

United States of America

Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009

Europe

Data Protection Act of 1998, Principle 5

EC Directive on Unfair Contract Terms in Consumer Contracts of 1993

WEBSITE ADDRESSES

AHIMA 'Fundamentals of the Legal Health Record and Designated Record Set' available at <http://library.ahima.org/doc?oid=104008#.WHznuRR0Uy4> accessed 16 January 2017.

American Medical Association 'AMA Continues Efforts to Improve Electronic Health Records' (2016) available at <https://www.ama-assn.org/content/american-medical-association-continues-efforts-improve-electronic-health-records> accessed 24 February 2017.

Bradley M Loucks J Macaulay J Noronha A and Wade M 'Digital Vortex: How digital disruption is redefining industries: an IMD and Cisco initiative' (2015) available at http://www.imd.org/uupload/IMD.WebSite/DBT/Digital_Vortex_06182015.pdf , accessed 5 March 2016.

Brandom R 'UK hospitals hit with massive ransomware attack: Sixteen hospitals shut down as a result of the attack' available at <https://www.theverge.com/2017/5/12/15630354/nhs-hospitals-ransomware-hack-wannacry-bitcoin> accessed 13 June 2017.

British Psychological Society 'Guidelines on the use of electronic health records' (2011) available at

http://www.bps.org.uk/sites/default/files/documents/electronic_health_records_final.pdf accessed 24 February 2017.

Casebooks Project 'History of medical record-keeping' available at <http://www.magicandmedicine.hps.cam.ac.uk/on-astrological-medicine/further-reading/history-of-medical-record-keeping> accessed 24 March 2017.

Department of Health 'Patient Rights Charter' available at <http://www.justice.gov.za/vc/docs/policy/Patient%20Rights%20Charter.pdf> accessed 13 March 2017.

Discovery 'HealthID: The technology that puts your patients' health records in your hands' (2016) available at <https://www.discovery.co.za/portal/individual/health-id> accessed 5 September 2016.

Econex 'The South African Private Healthcare Sector: Role and Contribution to the Economy' (2013) available at <http://www.mm3admin.co.za/documents/docmanager/f447b607-3c8f-4eb7-8da4-11bca747079f/00060290.pdf> accessed 11 June 2017.

FDA 'Draft guidelines on the use of Electronic Health Record Data in clinical investigation' (2016) available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm501068.pdf> accessed 28 March 2017.

Gary A Vawda Y and Jack C 'Health policy and legislation' (2013) *South African Health Review* available at <http://www.hst.org.za/publications/south-african-health-review-2012/13> accessed 24 September 2016.

General Medical Council 'Good Medical Practice' (2013) note 19-21 available at http://www.gmc-uk.org/static/documents/content/GMP_.pdf accessed 24 February 2017.

HPCSA Booklet 1 to 15 (2016) available at <http://www.hpcsa.co.za/Conduct/Ethics> accessed 23 July 2017.

HPCSA ‘My Rights and Responsibilities’ available at <http://www.hpcsa.co.za/Public/MyRights> accessed 23 July 2017.

HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ General ethical guidelines for health care professionals, Booklet 1 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%201.pdf accessed 23 July 2017.

HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Seeking patients informed consent: The ethical considerations, Booklet 4 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%204%20.pdf accessed 23 July 2017.

HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Confidentiality: Protecting and Providing Information, Booklet 5 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%205.pdf accessed 23 July 2017.

HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Ethical guidelines for good practise with regards to HIV, Booklet 6 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/ethical_rules/Booklet%206%20Gen.pdf accessed 23 July 2017.

HPCSA ‘Guidelines for Good Practice in the Health Care Professions’ Guidelines on the keeping of patient records, booklet 9 (2016) available at http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%209.pdf accessed 23 July 2017.

HPCSA ‘Guidelines for good practice in the Healthcare professions’ General Ethical Guidelines for Good Practice in Telemedicine, Booklet 10 (2014) available at

http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/conduct_ethics/Booklet%2010.pdf accessed 23 July 2017.

Health Systems Trust ‘Government paves the way for move towards paperless hospitals’ (2016) available at <http://www.hst.org.za/news/government-paves-way-move-paperless-hospitals> accessed 6 September 2016.

Hippocratic Oath ‘Classical Version’ available at <http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html> accessed 3 July 2016.

Kelly H ‘What to do if you Yahoo account was hacked’ (2016) available at <http://money.cnn.com/2016/09/22/technology/yahoo-hack-password-tips/> accessed 24 September 2016.

George C ‘Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services’ (2014) available at http://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_united_kingdom_en.pdf accessed 25 February 2017.

Moodley K ‘Patients as consumers of health care in South Africa: the ethical and legal implications’ (2013) *BMC Medical Ethics* available at <https://bmcomedethics.biomedcentral.com/articles/10.1186/1472-6939-14-15> accessed 2 April 2017.

MPS ‘Medical Records in South Africa: An MPS guide’ (2014) available at <http://www.medicalprotection.org/southafrica/advice-booklets/medical-records-in-south-africa-an-mps-guide> accessed 25 September 2016.

Oellermann I ‘Medical malpractice rife’ (15 March 2016) *The Witness* available at <http://www.news24.com/SouthAfrica/News/medical-malpractice-rife-20160314> accessed 14 August 2016.

O'Harrow R 'Health-care sector vulnerable to hackers, researchers say' *Washington Post* (December 25, 2012) available at

https://www.washingtonpost.com/investigations/health-care-sector-vulnerable-to-hackers-researchers-say/2012/12/25/72933598-3e50-11e2-ae43-cf491b837f7b_story.html?utm_term=.7a0265d17f7a accessed 22 February 2017.

Pagilery J 'Hackers selling 117 million LinkedIn passwords' (2016) available at <http://money.cnn.com/2016/05/19/technology/linkedin-hack/> accessed 16 August 2016.

Paul I 'Update: LinkedIn Confirms Account Passwords Hacked' available at <http://www.pcworld.com/article/257045/security/6-5m-linkedin-passwords-posted-online-after-apparent-hack.html> accessed 29 March 2017.

Snail SL 'Electronic contracts in South Africa – A comparative analysis' (2008) *Journal of Information Law and Technology* available at http://go.warwick.ac.uk/jilt/2008_2/snail accessed 19 February 2017.

The British Psychological Society 'Guidelines on the use of Electronic Health Records' (2011) available at http://www.bps.org.uk/sites/default/files/documents/electronic_health_records_final.pdf accessed 24 August 2016.

U.S Department of Health and Human Services 'Belmont Report 1979' available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> accessed 29 March 2017.

U.S Public Health Service 'Tuskegee study of untreated syphilis in the negro male' available at <https://www.cdc.gov/tuskegee/timeline.htm> accessed 1 July 2017.

World Health Organisation 'Electronic Health Records: Manual for Developing Countries' (2006) available at <http://www.wpro.who.int/publications/docs/EHRmanual.pdf> accessed 25 September 2016.

World Health Organisation 'mHealth: New horizons for health through technologies available' (2011) 7 *Global Observatory for eHealth series 6* available at http://www.who.int/goe/publications/goe_mhealth_web.pdf accessed 8 April 2016.