# Patient Access to Medical Records: Should Malaysia Widen Patient Access?

Thesis submitted in accordance with the requirements of the University of Liverpool

for the degree of Doctor in Philosophy (PhD)

By

Astrid Sinarti Hassan

September 2023

# Acknowledgements

This PhD journey would not have been easy without the support of many people. All praise to Allah for guiding me and giving me strength to complete my thesis. I am also profoundly grateful to my supervisory team as this thesis could not have been achieved and completed without their generous support and encouragement. To my primary supervisor, Dr Lucy Frith and co-supervisors, Dr David Horton and Dr Stuart Oultram, their supervision, comments, feedback and valuable insights during this entire research was hugely beneficial. I would also like to extend my sincere appreciation to all the staff in the Law School and the Institute of Population Health.

A big thank you to MARA organisation for its financial support which enabled me to pursue my study at University of Liverpool.

Most importantly, I would especially like to thank my husband, mother and sister who have provided me with countless support, inspiration and persistent encouragement. Thank you also to the rest of my family who stood by me throughout this challenging endeavour.

A special dedication to my son, Rayyan for his tolerance despite the challenges of parenting on my own in a foreign country while doing this research at the height of the Covid-19 pandemic.

# Abstract

Patient Access to Medical Records: Should Malaysia Widen Patient Access?

Astrid Sinarti Hassan

The Malaysian approach to patient access to personal medical records has been ambiguous. Currently, no legislation explicitly allows the right of access to medical records for Malaysian patients. The closest legislation that approximates this right is the Personal Data Protection Act (PDPA) 2010 but this only governs the manner and right of access to the data user and data subject thereby advocating data protection in general terms, which raises the question of whether the term 'data' applies to medical records. Even then, it is restricted to the private healthcare sector which forms only a small part of the Malaysian healthcare ecosystem. Despite guidelines from the Malaysian Medical Council stating that patients have the right to access their medical information, this analysis reveals several contradictions and contravening government regulations that suggest otherwise. Patients thus have no authority to access medical records as this authority belongs to doctors and hospital providers. As it stands, patient access to medical records can be granted only through a court order.

The objective of this thesis is to determine whether Malaysia should widen patient access to medical records and how this could be achieved. It examines three important aspects of widening patient access: the legal impediments to patient access and the current legislative and regulatory landscape in Malaysia; the ethical principles involved in widening patient access under which the doctor-patient relationship operates; and the changes needed to support access and how this would affect the doctor-patient relationship. It then develops a practical and coherent framework and recommendations based on legal and ethical perspectives to support the goal to improve patient access to their medical records. In doing so, the effect of the regulatory space on patient access to these records is also touched upon as it is an integral part if any changes are to happen.

The thesis concludes by detailing a set of legal and ethical recommendations for Malaysian authorities which may help improve the current legal position in recognising patients' rights to access their medical records. In doing so the recommendations are used to underpin a reform strategy aimed to shift the current paradigm of values and beliefs and make it a norm, initially by legislation but later by behavioural changes brought by the legislation.

# Table of Contents

## List of Tables



## List of Figures

# List of Cases

## Malaysian Cases

Abdul Razak bin Datuk Abu Samah v Raja Badrul Hisham bin Raja Zezeman Shah and Ors [2013] MLJ 34

Dr Soo Fook Mun v Foo Fio Na & Anor and Another Appeal [2001] 2 CLJ 45

Foo Fio Na v Hospital Assunta & Anor [1996] 6MLJ

Gurmit Kaur A/P Jaswant Singh v Tung Shin Hospital & Anor [2012] MLJ 260

Hassan Datolah v Government of Malaysia [2003] 5 CLJ 355

Hong Chuan Lay v Dr. Eddie Soo Fook Mun [1998] 7 MLJ

Kamalam a/p Raman v Eastern Plantation Agency (Johore) Sdn Bhd [1996] 4 MLJ 674

Lee Ewe Poh v Dr Lim Teik Man [2011] 4 CLJ 397

Norizan Bte Abd Rahman v Dr Arthur Samuel [2013] MLJ 385

Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors [2019] 9 CLJ

Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors; [2015] 1 CLJ 825

Perbadanan Nasional Berhad v Syed Omar Syed Mohamed [2011] 1 LNS 96

Sivarasa Rasiah v Badan Peguam Malaysia [2010] 2 MLJ 333

Tan Ah Kau v Government of Malaysia [1997] 2 AMR 1382

Tan Tek Seng v Suruhanjaya Perkhidmatan Perkhidamatan [1996]

Ultra-Dimension Sdn Bhd v Kook Wei Kuan [2004] CLJ 285

Zulhasnimar Hasan Basri & Anor v Dr Kuppu Velumani P & Ors [2017] LNS 1057

## Cases from other jurisdictions

Bolam v Friern Hospital Management Committee [1957] 1 WLR 582

Bolitho v City of Hackney Health Authority [1998] AC 232

Cobbs v Grant [1972] 8 Cal. 3d 229

McInerney v MacDonald [1992] 93 DLR

Montgomery v Lanarkshire Health Board [2015] UKSC 11

Mulley v Manifold [1959] 103 CLR 341

Re C (Adult: Refusal of Treatment) [1994] 1 WLR 290

# List of Legislative Instruments and Statutes

**Malaysian Statutes**

Civil Law Act 1956

Courts of Judicature Act 1964

Federal Constitution 2010

Government Proceedings Act 1956

Interpretations Act 1948 and 1967

Medical Act 1971

Official Secrets Act 1972

Rules of Court 2012

Personal Data Protection Act 2010

Private Healthcare Facilities and Services Act 1998

**Other Countries Statutes**

Access to Health Records Act 1990

Access to Medical Reports Act 1988

Convention of Human Rights Biomedicine 1997

Data Protection Act 1984

Data Protection Act 1998

Data Protection Act 2018

European Convention Human Right 1959

Freedom of Information Act 2000

Freedom of Information (Scotland) Act 2002

Health Insurance Portability and Accountability 1996

Hong Kong Personal Data (Privacy) Ordinance 1995

Human Rights Act 1998

Universal Declaration of Human Rights 1948

# List of Abbreviations

| | |
|---|---|
| ACPO | Association of Chief Police Officers |
| AHA | Access to Health Records Act |
| AMA | American Medical Association |
| CKAPS | Private Medical Practice Control, Division of Medical Practice |
| DPA | Data Protection Act |
| ECHR | European Convention for the Protection of Human Rights |
| EHR | Electronic Health Record |
| EMR | Electronic Medical Record |
| FOIA | Freedom of Information Act |
| FOISA | Freedom of Information (Scotland) Act |
| GDPR | General Data Protection Regulation |
| GMC | General Medical Council |
| HIPAA | Health Insurance Portability and Accountability Act |
| HIS | Hospital Information System |
| ICO | Information Commissioners Office |
| ICU | Intensive Care Unit |
| MCMC | Ministry of Communications and Multimedia Commission |
| MMC | Malaysia Medical Council |
| MoH | Ministry of Health |
| MSC | Multimedia Super Corridor |
| NEP | New Economic Policy |
| NHS | National Health Service |
| OSA | Official Secret Act |
| PALS | Patient Advice and Liaison Service |
| PDPA | Personal Data Protection Act |
| PDPD | Personal Data Protection Department |
| PHFSA | Private Health Facility Services Act |
| PIC | Preliminary Investigation Committees |

| | |
|---|---|
| RAND | Research and Development Cooperation |
| SAR | Subject Access Requests |
| SDM | Shared Decision Making |
| THIS | Total Hospital Information System |
| UK | United Kingdom |
| US | United States of America |

# Introduction

Medical records are official documents that contain the clinical details of an individual. This includes their medical history, diagnostic test results and care or treatment plan which are usually compiled by healthcare professionals.[1] Recently, healthcare provision has seen the care paradigm shift towards an emphasis on patient-centred care, resulting in a change in the patient's status from a passive recipient of medical care to a more active participant. This encourages the growing concept of patients as consumers and active stakeholders[2] which is reflected in the growing practice of patients having direct access to their records.

The clinical information provided by doctors to facilitate shared clinical decision-making can improve the patient's understanding of their health and the care provided to them.[3] In the United Kingdom (UK), policymakers have laid the foundation to promote active patient participation in clinical consultation that empowers patients in managing their health.[4] An example is how shared clinical decision-making is now considered standard and healthcare professionals work with their patients, combining professional expertise and the individual's preference and values to reach a decision about care.[5] Empowerment is the process of giving

---

[1] Maizatul Farisah Mohd Mokhtar, 'The Law and Challenges to Access Medical Records for Medical Negligence Claims in Malaysia' (2020) 26 Jurnal Undang-Undang dan Masyarakat 43, 43 .

[2] Michael K Gusmano, Karen J Maschke and Mildred Z Solomon, 'Patient-Centered Care, Yes; Patients as Consumers, No' (2019) 38 Health Affairs 368, 368 ; Sonali R Mirsha and others, 'Not Just a Receiver: Understanding Patient Behaviour in the Hospital Environment' (2016) Proc SIGCHI Conf Hum Factor Computer System 3103.

[3] Mohamed Alameddin and others, 'Physicians' Perspective on Shared Decision-Making in Dubai: A Cross-Sectional Study' (2020) 18 Human Resources for Health 2.

[4] National Health Service, 'Involving People in Their Own Health and Care: Statutory Guidance for Clinical Commissioning Groups and NHS England' (2017) 3 <https://www.england.nhs.uk/wp-content/uploads/2017/04/ppp-involving-people-health-care-guidance.pdf>, accessed 1 February 2020.

[5] National Institute for Health and Care Excellence (NICE), 'Shared Decision Making' <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making>, accessed 1 February 2020.

people more autonomy and increasing their awareness, skills and knowledge so that they can make better decisions about their well-being.[6] Patients can be empowered through information and communication technologies to participate in clinical decisions through the acquisition of knowledge and information. Empowering patients to be more autonomous through self-care and the application of self-knowledge and awareness are associated with higher patient satisfaction with healthcare services.[7] One way that information can be shared with patients is by allowing them to access their medical records. According to Professor Alf Collins, a national policy adviser in person-centred care:

> By involving people in decisions about their health and care we will improve health and well-being, improve the quality of care and ensure people make informed use of available healthcare resources. Involving people in their own health and care not only adds value to people's lives, it creates value for the taxpayer. The challenge now is to shift the focus of care and support services from 'what is the matter with you?' towards 'what matters to you'?[8]

The doctor who acts as the traditional 'gatekeeper' of medical records plays the role of controlling information because the physical ownership of medical records rests with them.[9] Thus, the medical records has been established as the property of the hospital providers and remains so under the jurisdictions of many countries including Malaysia[10] but unlike Malaysia, patients in countries like the UK and US are entitled under their data protection legislation to view their original records and to obtain copies of them.[11]

---

[6] DH Lau, 'Patient Empowerment- a Patient-Centred Approach to Improve Care' (2002) 8 Hong Kong Medical Journal 372.

[7] Traber Davis Giardina and others, 'Patient Access to Medical Records and Healthcare Outcomes: A Systematic Review' (2014) 21 Journal of the American Medical Informatics Association 737.

[8] National Health Service, 'Involving People in Their Own Health and Care: Statutory Guidance for Clinical Commissioning Groups and NHS England', 3.

[9] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports* (2006), cl 1.12.

[10] Ibid.

[11] Refer to Data Protection Act 2018; Health Insurance Portability and Accountability Act 1996.

Although the information in the medical records belongs to the patient, as technically the patient owns the personal information under the universal right to self-information,[12] medical records are also the intellectual property[13] of the healthcare providers that created and contributed to them. Access to one's own medical records remains a challenge in many countries including Malaysia due to this ambiguity of ownership. As access is tightly controlled by the authorities such as healthcare providers, they have a legal obligation to protect the confidentiality of this asset. Potential conflicts of interest arise as direct access to medical records held by authorised bodies such as hospitals and healthcare providers make them more accountable and liable to negligence claims.[14] In *Nurul Husna Muhamad Hafiz & Anor v Government of Malaysia*, the Court held that:

> The prevalent common practice among medical professionals and hospitals is to refuse to give copies of [the] patient's medical records unless ordered by the court to do so. This has necessitated the filing of applications by patients seeking [the] court's intervention to order [the] production of the medical records. In most cases, when the application comes for hearing, the respondent throws in the towel and agrees to produce copies of the medical records sought. In a handful of cases, there is resistance and the court determines the issue to order production. This guarded conduct of the medical professionals and hospitals has caused patients to incur avoidable costs and delays by filing originating processes for an order for discovery of their medical records. [15]

As the concept of patient-centred care grows globally aligned with empowering patients to use information to improve their health outcomes, so does the need for existing legal standards to adapt or be replaced by new ones. To focus on issues of access to medical records, distinctions between access and disclosure need to be considered, as they tend to be subsets of patient-centred care but governed by distinct legal regimes. For example, in the UK, the law on

---

[12] European Convention Human Rights 1959. Article 10 of the Convention provides the right to hold opinions and to receive and impart information and ideas without interference by public authority.

[13] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.12.

[14] Mohd Mokhtar, 'The Law and Challenges to Access Medical Records for Medical Negligence Claims in Malaysia', 49.

[15] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors* [2015] 1 CLJ 825 [13].

disclosure is more established via provisions such as the Data Protection Act, the common law duty of confidentiality and duty of candour. However, in Malaysia, there is a lack of discussion and legal standing regarding patient access to their medical records as a subset of patient-centred care as the country usually lags behind the movement to improve patient autonomy and their right to information compared to other developed countries.[16] As a clinician who worked previously in Ireland and currently in Malaysia, I personally attest to the differences in the standard conduct of practice between the two healthcare systems in which patient autonomy remains undervalued in Malaysia in comparison to Ireland. Currently, routine access to medical records and its regulation in Malaysia are still governed and restricted by legal means and I have experienced that a request for access usually provokes a negative reaction amongst healthcare professionals in Malaysia due to fear of litigation, although there is little evidence to support these fears.[17] Legal means include the formal procedures used by different parties, including patients, to procure their medical records through methods of discovery and subpoena (see Section 2.4).

In Malaysia, the PDPA was passed to protect personal information, but it has limited application to patients accessing their medical information. In contrast, access to patients' medical records has been liberalised and widened in many countries such as the US with the Federal Health Insurance Portability and Accountability Act (HIPAA) 1996. In the UK, various laws had been passed including the current Data Protection Act 2018, the Access to Health Records Act 1990 and the Access to Medical Reports 1988 which allow patients to access their medical records. Unlike such countries, Malaysia has been less reformative in the matter.

[16] Yew Kong Lee and others, 'Shared Decision-Making in Malaysia: Legislation, Patient Involvement, Implementation and the Impact of Covid-19' (2022) 171 Z Evid Fortbild Qual Gesundhwes 89, 90.
[17] HS Arvinder-Singh and Abdul Rashid, 'The Intention to Disclose Medical Errors among Doctors in a Referral Hospital in North Malaysia' (2017) 18 BMC Medical Ethics 1, 8 ; Mohd Mokhtar, 'The Law and Challenges to Access Medical Records for Medical Negligence Claims in Malaysia', 47.

In addition, there are no data recorded or published, either in hospitals or at national level, on patient access to medical records and whether this has been refused. Neither is the information readily accessible using a freedom of information request. To date, Malaysia has no federal legislation on the right to information,[18] where 'freedom of information' would refer to the right given to the public to seek information from government bodies (see Section 3.3).

Part of the challenge in this thesis is that the nature of the problem appears to be obvious, but there is no strong evidence to measure the scale of this issue. This lack of information is fortified by the fact that there are no services in any of the hospitals that support this practice to provide patient access to their medical records. Despite the MMC's guideline on patient access, it is a general rule that doctors and hospital providers are not allowed to grant patient access to medical records, which highlights the difficulty in establishing the magnitude of the problem. The standard practice is to apply for medical reports, which are issued after a request has been made by patients. It is likely that patients themselves do not request medical records as they are offered medical reports instead. Therefore, the physical form of medical records is not expected to be accessible by patients. However, there are no published reports on requests and refusals pertaining to this. Therefore, this thesis inferred that the case of *Nurul Husna*[19] illustrated how the plaintiff was first required to obtain a court order prior to accessing her medical record, as this was initially refused by the hospital. There is also a lack of literature on patients' right to access their medical records in Malaysia, thus it is difficult to establish the extent of the problem. However, the lack of literature suggests that this subject has never been fully analysed in the bioethical and legal scholarship and so this thesis provides, for the first

[18] Muhamad Izwan Ikhsan and Lenny James Matah, 'Enacting Freedom of Information Act in Malaysia: A Cost-Benefit Analysis' (2022) 7 Malaysian Journal of Social Sciences and Humanities 1.
[19] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

time, a dialogue using both legal and ethical frameworks to justify wider access to medical records for patients in Malaysia.

**Background**

The research question of this thesis is:

> Should Malaysia grant wider access to medical records for patients and how could this be achieved?

There is no specific legislation or statutory right that allows the right of access to medical records for patients in Malaysia. The Malaysian healthcare system is composed of both public and private sectors and these sectors are governed separately in a dual-tier system using distinct systems of laws and regulations. The Ministry of Health (MoH) is responsible for both sectors, but the majority of healthcare is provided by the public sector.

There are two tranches of law that indirectly concern access to patient information in Malaysia. The PDPA 2010 (Act 709) was passed to protect the personal information of citizens, providing data protection and privacy in general. However, there are several flaws within this Act, including that it does not specifically mention 'data' in the form of medical records. This is in contrast with the UK's Data Protection Act which defines data to encompass 'health records'.[20] Section 3(1) of the PDPA also states that this 'Act shall not apply to the Federal government and State Governments'. Hence, the law has failed to recognise the general right of a patient to access their medical records, including at public hospitals. The PDPA has also failed to elaborate on how doctors should lawfully practise. The lack of provisions that are concise and specific to healthcare creates an ambiguity about how data users (the doctors) and data subjects

[20] Data Protection Act 201*8,* s 205(1). Section 68 was repealed by DPA 2018.

(the patients) should act and practise. This is then further compounded by the lack of enforcement of the PDPA.

The second piece of legislation is the Private Health Facility Services Act (PHFSA) 1998 (Act 586) and its Regulation 44 of PHFSA 2006 are only applicable to private facilities. This Act deals with the licensing of private healthcare facilities including private hospitals and dictating how they should be managed. It concerns itself with ensuring the quality and safe services that these facilities provide to the clients. Therefore, PDPA does not apply to state or federal governments and the PHFSA, which is only applicable to private healthcare facilities, and essentially limits the law that may apply to public hospitals. This results in inconsistencies in the current legal framework of the two-tiered system. Meanwhile, Regulation 44 of PHFSA 2006 states that patient access to medical records must be obtained by a court order.

The inconsistencies and complexities between public and private healthcare systems are further illustrated in the process of providing patient access to medical records. The right to access is not clearly articulated in the public sector. The main regulatory body which governs patient access to medical records is the Malaysian Medical Council (MMC) and this is stated in its guidelines. It is a core regulatory body under the patronage of the Ministry of Health, of which the functions are to register medical practitioners intending to practise in the country and to ensure that practice is of reasonable and acceptable standard as regulated by their own disciplinary committee. [21] The MMC Guideline of Medical Records and Medical Reports calls for 'open' access based on 'good faith'.[22] Clause 1.7 of the Guideline of Medical Records and Medical Reports in the MMC Guidelines, which governs the public sector states that it is generally acceptable to allow patients to access their medical records for a 'legitimate purpose'

[21] Wan Abdullah and Nik Rosnah, 'Medical Regulation in Malaysia: Towards and Effective Regulatory Regime' (2002) 21 Policy and Society 94, 101.

[22] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.7.

and in ‘good faith’. Thus, under the MMC Guidelines, a patient who has attended a public hospital may theoretically be able to exercise their right to access medical records based on ‘good faith’ as determined by the hospital. The same patient will be declined access at a private hospital as the PHFSA stated that patient access requires a court order. Such an order requires some effort and expense, thus, attenuating the willingness of patients to seek their records.

The dual-tiered system invites discrepancies as legislation created to enforce the law cannot be applied to the major provider of healthcare; the government. To make matters more complicated, each tier of Malaysia’s two-tier healthcare system is governed by different regulatory bodies. The MoH and the MMC have authority which does not extend to private-run clinics and hospitals. As statutory bodies tasked with rules and regulations imposed by the provisions of the Medical Act 1971, they are authorised to exercise a range of important powers. Under this Act, the MoH governs how the MMC exercises its powers including the endorsement of patient access to their medical records. [23] The MMC’s authority to create healthcare policies in Malaysia is, paradoxically, now enshrined in a non-binding guideline (‘the Guidelines’) on medical records. Even though there has been no literature to suggest MMC as a self-regulatory body, defined by Baldwin as ‘a group of individuals [which] exert[s] control over its own membership and their behaviour’,[24] it operates by delegating the regulatory function to bodies beyond the state. Unlike the General Medical Council in the UK, there are no public representatives on the members of committee in MMC Malaysia. This encourages exclusive self-regulation by professionals, which can be biased and partial to the regulatees. For example, the MMC may be considered as a body which acts to enforce self-regulation on health practitioners to ensure that the practices within the healthcare services are within

[23] Medical Act 1971, s 4F.

[24] Robert Baldwin, Martin Cave and Martin Lodge, 'Self-Regulation, Meta-Regulation, and Regulatory Networks', *Understanding Regulation: Theory, Strategy, and Practice* (Second edn, Oxford University Press 2011), 2.

accepted moral and ethical norms, but only according to medical professionals. The guidelines outlined in the Good Medical Practice allow registered practitioners to practise and be trained in their professions without the need of an external regulation (see Chapter 7).[25]

The MMC is non-prescriptive and does not have a strong legislative mandate; it is but a 'shadow of potential government regulation'[26] which challenges the practice for patients to seek medical records as it is the only guideline specifically acknowledging the right to access for patients. However, it appears that the guidelines deviate from the practice dictated by the MMC and these deviations can further frustrate the rights and protections of those patients seeking access to their medical records (see Chapter 2). It has been described by Baldwin that an indicator of regulatory failure includes regulation that offers a 'more technocratic and safe mode of control',[27] and it is appropriate to consider whether this might contribute to weakness that lies within the MMC.

As illustrated above, the regulatory domain on widening patient access to medical records in Malaysia is contradictory and inconsistent, hence the difficulty in enforcing the law pertaining to the issue. Scholarly discussion of why patient access to medical records is defaulted through a court order is required in order to clarify what is contributing to the regulatory failure in patient access to medical records. It is important to examine and integrate the theories of regulation to the practice in Malaysia and use this as a platform to propose recommendations which will be tailored to the Malaysian context.

As mentioned earlier, the MMC Guidelines recognise patients' right to their medical records, but the exercise of right is almost non-existent in Malaysia. Unlike the UK case in

---

[25] Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Good Medical Practice* (2019), 4.
[26] Baldwin, Cave and Lodge, 'Self-Regulation, Meta-Regulation, and Regulatory Networks', 21.
[27] Ibid 17.

*Montgomery,*[28] Malaysia's existing legal framework using the MMC's Guidelines is not subject to binding law. It is not yet known whether Malaysia will have the chance to legalise regulations issued by regulators like the MMC, because expectations set forth in Malaysian judicial rulings using the MMC's regulations have never been put into practice, including patients' right to access their medical records (see Chapter Two). Due to the contradictions in the provisions, the existing rules have generated ambiguity and inconsistencies which may make it difficult for MMC guidelines to be enforced.

While there is a lack of evidence to support the reasons for this, I will propose several factors from my personal experience as a clinician serving in the Malaysian healthcare system which may aggravate the problem. These factors include the hierarchical structure of the healthcare system, the doctor-patient relationship, a lack of awareness of patients' rights, a lack of empowerment and discussion of patient-centred care and the routine practice of accessing medical records by court order. Case laws in Malaysia have shown that patients are unable to access medical records directly unless obtained via a court order.[29] In the case of litigation, while medical records are proposed as legal documents for clinicians, open records allow the plaintiff (mainly the patients) to use the documents to make a case against the clinician or institution. Consequently, the plaintiff would ultimately petition the court for an order to grant access to the records.[30] As an essential piece of evidence, the medical record is a vital tool used in court to determine the outcome of the case.[31] Therefore, I hypothesise that the culture of medical records and access in the context of a negligence claim feeds into the fear amongst medical practitioners and their institutions due to this strong association of legal accountability.

---

[28] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

[29] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors; Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors [2019] 9 CLJ.*

[30] Rules of Court 2012, order 24, r 10.

[31] Puteri Nemie Jahn Kassim, *Law and Ethics Relating to Medical Profession* (International Law Book Services 2007), 182.

The obstacles to patients accessing medical records might be a deliberate attempt to discourage litigation, as opposed to a lack of awareness of the practice as a patient-centred aspect of care that endorses an individual's right to information about his or her healthcare. While there is no empirical evidence to support this hypothesis, the situation might be similar to that in a Japanese study which reported that 40% of doctors would reject a request to access, with half of them saying that a decision would be based on the patient's reason for the request.[32]

The current guideline and legal standing are inadequate to support patient access to their medical records. In Chapter 2, this thesis discusses the heavy reliance of the Malaysian system on a rigid legal process with access secured for purposes related to litigation as opposed to a general and accessible right. A possible consequence of restricting access is limiting access to justice; patients who seek to determine if they have a potential negligence claim against a doctor and are considering legal action could be deterred from doing so because access to their medical information is tightly controlled.

While the legal component of access is important to the analysis in this thesis, my study also includes ethical scholarship on this issue. This is important due to the complex regulatory space relating to access to records. Before I illustrate the regulatory space in Malaysia, let me define this concept. Hancer, in *Capitalism, Culture and Economic Regulation*, defined regulation as 'features of any system of social organisation, for we recognise the existence of social order by the presence of rules'. [33] He described regulation using the analytical notion of regulatory space and how national, political and legal contexts influence the shape of the regulatory space and the distribution of power within it. Factors such as a lack of awareness of patient rights and discussion on patient-centred care are inextricably linked to the different values and goals of

[32] Hiroyuki Hattori and others, 'The Patient's Right to Information in Japan- Legal Rules and Doctor's Opinions' (1991) 32 Social Science and Medicine 1007.

[33] Leigh Hancher and Michael Moran, 'Organising Regulatory Space', *Capitalism, Culture and Economic Regulation* (Clarendon Press 1989), 148.

the different actors (doctors and patients) and their level (or lack thereof) of education on the matter. For example, doctors in Malaysia enjoy an exalted status in the hierarchy of the healthcare system highlighting the imbalance in power between doctors and their patients (see Chapter 3). [34] Compared to the UK, the lack of awareness of the concept of openness and transparency to promote accountable healthcare may compromise quality, safety and patient outcomes. Medical schools in Malaysia have only recently introduced ethics and communication to their core curriculum.[35] This 'lag' in progress shapes a regulatory space that inherently rejects the justifications to widen access. For example, a doctor trained and practising in Malaysia, due to the lack of appreciation of standard framework in the ethical-legal scholarship on the domain of patient access to medical records, might not comprehend why medical records should be accessible to patients for a variety of reasons such as autonomy and improved patient's satisfaction due to lack of experience and perspective outside the Malaysian context.[36] Thus, the regulatory failure that is unique to Malaysia plays an important role in influencing the practice on patient access and explains why restrictions of access have prevailed. Later in this thesis, I will explore some concepts drawn by Julia Black's work on decentring regulation which are significant to explain why there is a regulatory failure in Malaysia in this particular domain.

Values and sets of behaviours should be based on the concept of principlism identified by Beauchamp and Childress[37] as having four principles: (1) autonomy, (2) beneficence, (3) non-maleficence and (4) justice. Their book *Principles of Biomedical Ethics* was first published in

[34] Academy of Medicine Malaysia, 'Ethical Professional Practice Guidelines' 2016), accessed 18 July 2022.
[35] Faculty of Medicine Universiti Teknologi MARA, *Master in Medical Ethics and Medical Jurisprudence* (Universiti Teknologi MARA).
[36] Stephanie N D'Costa, Isla L Kuhn and Zoë Fritz, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences' (2020) 21 BMC Medical Ethics 1.
[37] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (7th edn, Oxford University Press 2013).

1985. These four principles are considered to be '*prima facie*', or non-absolute.[38] Prima facie means unless it conflicts with another moral principle, the principle is binding.[39] Principlism provides medical professionals with a guide for making difficult bioethical decisions in everyday practice. Part Two of this thesis uses these principles to justify wider access to medical records for patients, with a discussion to explore the reality of their utility in everyday clinical practice. Malaysia does recognise and utilise principlism, at least in theory. It is part of the Ethical Professional Guidelines of the Academy of Medicine in Malaysia.[40]

To assist patients' self-management to achieve patient-centred care, healthcare providers must change their responses and behaviours to embrace a patient-centred approach. The focus is on developing a relationship with patients, which would necessitate training in skills such as motivational interviewing, cognitive behavioural methods and collaborative goal-setting while considering the work and values of the health professionals.[41] The law is often associated with the values and beliefs of the society, but designing legal processes in ways that encourage the parties involved to be responsive and reflexive toward one another could be challenging.

**Aim and objectives**

The aim of this thesis is to examine whether Malaysia should widen its access to medical records for patients and how this could be achieved. By examining the dynamics and paradigm of the regulations, their engagement and execution, this thesis identifies the gaps, unpacks challenges and proposes recommendations as part of its objectives. It proposes a practical and

[38] Oliver Rauprich, 'Common Morality: Comment on Beauchamp and Childress' (2008) 29 Theoretical Medicine & Bioethics 43, 44.
[39] Raanan Gillon, 'Medical Ethics: Four Principles Plus Attention to Scope' (1994) 309 British Medical Journal 184, 184.
[40] Academy of Medicine Malaysia, 'Ethical Professional Practice Guidelines'.
[41] Hui Chin Mah, Leelavathi Muthupalaniappen and Wei Wen Chong, 'Perceived Involvement and Preferences in Shared Decision-Making among Patients with Hypertension' (2016) 33 Family Practice 296, 296.

coherent theoretical framework through a set of recommendations based on legal and ethical perspectives by examining important aspects of widening patient access to their medical records. It also examines the legal impediments by looking at the current legislation and regulations in Malaysia and then, using the ethical framework of principlism, it advocates wider access to these records. It compares the current Malaysian legislation and guidelines with those of the UK and discusses the challenges and measures needed to support this objective, including how this could affect the doctor-patient relationship.

A comparative analysis between the legal rules in the UK and Malaysia is conducted (Chapter 3) to explore the more established statutory position in the UK with that in Malaysia which has no substantive legislation on access to medical records. This will guide Malaysia to reflect on and resolve this issue to a higher standard of practice than the MMC Guidelines and allow patient access to their medical records without the need for a court order. This study will also propose a bespoke legal and ethical conceptual framework for Malaysia that works and aspires to encourage a modern and state-of-the-art health ecosystem.

**Sub-research objectives**

To guide this work, three sub-questions were formulated to answer the main aim of this thesis:

1. What are the legal impediments to enabling wider access to medical records for patients in Malaysia and how does this compare with the UK?
2. What ethical theories and applications can be used to justify the need to widen patient access to information in medical records and applications?
3. What are the legal and regulatory changes required to support the objective of granting wider access to medical records to patients?

**The scope of research**

This thesis will develop a practical and coherent theoretical framework through a set of recommendations based on legal and ethical perspectives to widen access to medical records for patients. It considers the legislative and regulatory background in Malaysia, or lack thereof and compares them with the current framework in the UK. Using an ethical framework to justify wider access, I argue that Malaysia not only requires a change of legislation but a more universal approach harnessing moral and ethical motivation by exploring the regulatory challenges in this regulatory space. To harness regulatory levers and tools beyond the state and throughout the domain of patient access, I will articulate the challenges of reform and propose recommendations that are informed by the legal, cultural and ethical complexities involved. While there is a need to progress the concept of governance in the day-to-day delivery of care to patients, I will also make recommendations that address the complexity of the regulatory space using both legal and ethical frameworks. The recommendations will be in alignment with the justification to widen or not widen patient access to medical records, which will be answered by the application of ethical theories.

Within this regulatory space, this thesis also attempts to discuss if specific legislation is needed to bring about a paradigm shift in the regulatory space to a more non-state involvement, concurrently allowing a regulatory realignment of social and legal reforms. While specific legislation allowing wider access would address this practice, I will argue that legalisation only provides one lever to achieve wider access to medical records. As a piece of legislation might not be as effective in changing the values of practice, especially if a society is not culturally ready, the purpose of this thesis is to create holistic recommendations to improve the practice in line with the current mindset by promoting the ethical reasons for the practice to become standard and necessary.

To achieve this, the thesis is organised into nine chapters:

Following this introduction, **Chapter 1** explores the general concept of medical records which includes the definition and types of records, the digital application of technology and the aspects of patient use on health records in the NHS healthcare setting. I will also describe their role as an evidentiary document in court and provides an in-depth analysis of the social dimension of medical records as well as the role they play in society. Aiming to depict a muti-dimensional discussion to explore what medical records are, their functions, and their roles as a form to communicate and plan patient's care, I will also describe medical records as a powerful tool which can influence both political and social outcomes using the concept of governmentality. I claim medical records have evolutionary roles which can act as a powerful and accountable tool that serve different functions in society and need to be distinguished and viewed as a technology of power that influences how people think, act and form relationships. As an autonomous healthcare professional myself, I strongly believe that medical records can be a form of social control, where these bodies of knowledge are used by those who 'know how' to provide information which can be of interest to the nation. It is not only a device known to be a repository of information, but it can also have a political role to drive a social construct of communication in both law and medicine. I will portray how doctors provide information and use medical records as a tool to communicate to other providers, as a legal and accountable document as well as a statement of truth in court, that provides a map of the health journey and trajectory of patients. It is thus important to recognise the type, function and social significance of medical records, to shed light on the potential benefits if access were allowed amongst different stakeholders including patients, and to support the arguments in this thesis that access can lead to more advantages than disadvantages.

**Chapter 2** focuses on patient access to records and the regulatory bodies and actors involved in its management. The section will start by introducing the Malaysian legal system and the current process for obtaining medical records. The legal and regulatory arrangements are then discussed by providing a short history of the legal developments around access to records, the legal position of access as well as its legal challenges. It focuses on the limitations of the present legislation, MMC Guidelines and other related guidelines.

In this chapter, I have configured the material around the legal framework and whether the current legislation is effective in protecting patient access to medical records, analysing and focusing on the relevant and most important legal mechanisms that exist which control patients' access to their medical records. I will examine the PDPA fundamentals and how this is relevant for accessing medical records, as well as explaining whether it is ineffective as a legal protection for patient access to medical records. I will then consider whether PDPA as part of the legislation only plays a supporting role. This chapter will also examine the soft laws and other non-prescriptive guidelines that are not enforced by law like the MMC guidelines as part of the foreground in the regulatory picture. After analysing the legal impediments to why the default practice of patient access to their medical records is through a court order, I will then conclude why the current legislation and the current guidelines lead to a non-explicit mandate for protection of this right.

**Chapter 3** examines the legal position using a comparative analysis of patient access to medical records in the United Kingdom. The main reason for the comparison is the strong historical link between Malaysia, as a Commonwealth country, and the English common law. The Malaysian legal system is predominantly structured according to the English law, the UK system is more developed and material is abundant on the matter. Taking the UK as a country of comparison is also based on the reliance whereby if a written law is lacking (Civil Law Act),

Malaysia will adapt its own law based on the UK common law with local modifications. It explores the legal regulations which shape the framework in the UK from a historical perspective as this might shape how the legal framework in Malaysia could mature. I also draw on academic commentaries on how the legal framework functions. Subsequently, an analysis of the English common law is presented which distinguishes Malaysian guidelines from the UK law through highlighting the fundamental differences between these two countries. The comparative analysis of the statutory framework and case law is to later determine whether Malaysia should adopt the UK as a model to reform the practice. To conclude, lessons from the UK law and related case laws which may be adaptable to Malaysia are drawn and discussed.

The next three chapters make up Part two of the thesis.

**Chapter 4** provides an introduction to the main ethical theories with an emphasis on principlism as developed by Beauchamp and Childress. I introduce the history which led to the creation of principlism and its application for resolution of conflicts, to answer my research question. I also introduce some clinical concepts and themes related to access to medical records and use this as a framework to discuss widening patient access to their medical records. Principlism is used to underpin my evaluation of the current rules and principles on patient access to medical records. As Beauchamp and Childress state, 'the physicians now face a dilemma, because of the conflict between demands of respect for autonomy and demand of beneficence'.[42] Competing interests that struggle to achieve a logical conclusion will lead to inherent conflicts which I aim to unpack as one principle may take precedence over another. The values and beliefs must be justified through balancing the act of ethical principles[43]

[42] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (5th edn, Oxford University Press 2001), 179.
[43] Henry S Richardson, 'Specifying, Balancing, and Interpreting Bioethical Principles' (2000) 25 Journal of Medicine and Philosophy 285.

between the two main actors as doctors and patients have different interests. Using the framework of ethical theories such as principlism, I am able to answer my research question whether we should widen patient access to medical records in Malaysia. As enhancing patient autonomy by information transmission and widening access provides parallel themes, these established concepts will be used to justify widening patient access from an ethical perspective.

In **Chapter 5**, I provide ways of approaching these ethical conflicts that may be encountered in everyday practice and subsequently provide an analytic framework by integrating ethical theories to determine whether widening patient access to medical records is ethically justifiable. Several themes are categorised under the bioethical principles of principlism which includes informed consent, illustrated as a legal and ethical necessity to respect patient autonomy. I also intend to categorise beneficence/ non-maleficence and group them from both the patients' and doctors' perspectives. I aim to use the model of patient-centred care to propose an argument within the framework of beneficence and the doctor's paternalistic role in the framework of non-maleficence. I will illustrate that the current regulation may be due to the interplay between different conflicts and different stakeholders. I will emphasise the ethical principle of respect of autonomy as a central tenet of information transmission and how this can translate into a spectrum of legal necessity in informed consent and other concepts. I will then justify widening patient access using the act of balancing and specification, exploring both patient's and doctor's perspectives using information transmission as the specific norm and medical records as a tool or medium of that information transmission.

**Chapter 6** answers the main research question of whether Malaysia should widen patient access to medical records. I will engage the ethical theories framework described in earlier chapters to help evaluate the principles of patients' access. My intention is not to go into great depth on ethical moral theories, but to introduce and discuss ethical theories that can be applied

to justify widening patient access. Hence, I intend to mainly use the framework of principlism and categorise under each principle by elaborating and focusing on issues relating to patient access and discussing the cases both for and against wider access. Several concepts are used to explore the complexities of the doctor-patient relationship including medical paternalism and therapeutic privilege to reveal the conflicts of interest between doctors and patients. This is in anticipation of a discussion on how the arguments against widening access do not outweigh the arguments for it. I will also use two other ethical theories: deontology and utilitarianism, to consider whether these theories also concur with principlism and whether we should or should not widen patient access to medical records, using an ethical lens.

As a clinician myself, using the doctor's perspective, I am aware that there is a valid argument and good reason as to why restricting patient access to their medical records has become the norm in clinical practice in Malaysia. Providing an ethical analysis using this main framework enables a balanced and counter-argument that would justify whether patient access to medical records should be widened despite conflicting interests between doctors and patients.

Part Three starts with **Chapter 7** where I map out the regulatory domain in Malaysia and recommend strategies to improve and facilitate wider access for patients. I briefly discuss contributing factors that influence the regulatory space in Malaysia and its complexity which may be reflective as well as distinct social hierarchy and healthcare providers continuing to enjoy a higher social status that may contribute to the shaping of the regulatory domain on patient access to medical records in Malaysia.

In order to propose recommendations for improvement, it is important to examine the regulatory space and discuss how regulation and the regulatory context has an influence on the practice of medical records access in Malaysia. Conceptually, I will be exploring Julia Black's work on regulation, which I find an interesting approach to explain the existence of regulatory

failure in Malaysia due to the presence of tension between the different actors that occupy this regulatory space. To consolidate my arguments on the regulatory space, I will revisit how the Malaysian Medical Council and the Ministry of Health as regulatory bodies provide asymmetrical and inconsistent implementation of the regulation.

I will also consider whether legislation is adequate as a tool for reform. A legal mandate can only validate certain kinds of behaviour, as regulation usually comes from the state of law and influences certain actions and activities of the actors. Perhaps the need to change the mindset of stakeholders/actors' attitude will overcome this issue. In short, the chapter will conclude that legislation per se may not be adequate, but the overall necessity of shifting the mindset of actors by putting control back to society will perhaps lead autonomous actors influencing this regulation by focussing on a set of goals that comply with patient autonomy and patient-centred care.

**Chapter 8** sets out the recommendations, which are based on the legal analysis in Part One and the ethical framework from Part Two. Malaysia should provide wider access to medical records by creating a meaningful set of holistic reforms, with several recommendations that may be particularly effective in improving the current ambiguity in recognising patients' right to access. It is important to not just merely adjust the laws but rather to reconfigure the regulatory regime through both a state level and non-state level approach. It offers a model to justify and regulate the practice of wider access to medical records, aligned with the current mindset to provide patient-centred healthcare.

**Chapter 9** summarises the arguments and concludes that reshaping regulations on access to medical records and information in Malaysia should not just be restricted to laws that are determined by the state, but also strengthen the ethical justification through the introduction of the concept of non-state approaches which would indirectly achieve the aim to improve patient

access to their medical records. The cultural differences will still be ingrained and how we practise patient access to medical records in the future will remain a unique feature in Malaysia. However, this practice does require reform and this thesis for the first time brings to fore that widening patient access to medical records is ethically the right thing to do in Malaysia.

Thus, this thesis provides original contribution to the literature. As emphasised earlier, there are minimal published studies or formal discourse on patient access to medical records in Malaysia. This thesis aims to justify widening patient access using an ethical approach of a principlism framework to answer the research question. It also explores in detail, and for the first time, the causes and effects of the Malaysian regulation on patient access to medical records, in which guidelines as well as the discrepancies in the relevant case laws are discussed. Another novel contribution of this study is the comparative analysis between Malaysia and the United Kingdom in matters pertaining to patient access to medical records. This thesis also identifies the loopholes and gaps in the existing legislation in Malaysia as well as its soft laws. The impact of this study is to conclude that these regulations, as compared to another country like the UK, have an impact on access, i.e. it remains restricted in Malaysia and requires a court order.

Another contribution of this thesis is to explore the issue through an ethical scholarship which encourages a more critical perspective, rather than uncritically following the notion that patients have rights, even though such rights are legitimately practised elsewhere such as in the UK. This is the first instance whereby patient access to medical records is being subjected to Beauchamp and Childress's ethical principles analysis. It answers the very elemental question of why patient access to medical records should be widened, using the principlism framework which has not previously been used to answer this question. Using principlism to justify why we should or should not widen patient access, this research facilitates a universal approach to

this issue which transcends different cultures and countries, whether or not the practice is already well-established or lawfully in place in that country.

The concept of regulatory space on this issue is also unprecedentedly applied to study the characteristic differences that are engrained in Malaysian society, which allows the thesis to put forward original recommendations to address the unique factors influencing regulation on patient access to medical records in Malaysia.

**Conclusion**

This thesis aims to justify wider patient access to medical records using an ethical lens and to recommend holistic reform to the regulation of medical records that will improve medical practice and encourage patient empowerment in Malaysia. It provides a much needed and timely discussion to improve patient access to medical records as well as enhance the overall ethical aptitude and patient empowerment in Malaysia in line with other modern healthcare systems.

# PART ONE: MEDICAL RECORDS AND THEIR REGULATION

# Chapter 1. Medical records: definition and functions

## 1.1 Introduction

This chapter explains what medical records are, the different types, their functions and their importance not only in the healthcare setting but to society at large. It discusses the versatile roles of medical records. Different healthcare stakeholders perform different functions, providing information and communication for a variety of purposes including medical education, research and legal protection. However, their primary role is still to communicate and plan patient care. According to Huffman, medical records are 'a compilation of pertinent facts of a patient's life and health history, including past and present illness(es) and treatment(s), written by the health professionals contributing to that patient's care. The health record must be compiled in a timely manner and contain sufficient data to identify the patient, support the diagnosis, justify the treatment, and accurately document the results.'[44]

Wrapped in Huffman's definition, this chapter will examine the various types of medical records, be it their physical (handwritten or typed) or electronic forms. Medical records are not a single object and different parts will be produced at different times in different places to reflect the current status of the patient depending on the point of care. For example, a medical record in the emergency department implies the patient is acutely ill and requires immediate attention whereas a clinic suggests a non-acute patient be treated as an outpatient. This chapter will also describe other significance of medical records, such as at the political and sociological levels.

[44] Edna K Huffman, *Medical Record Management* (9th edn, Physicians' Record Company 1990), 596-597.

What makes medical records an interesting subject to discuss are the versatility and flexibility that they have demonstrated. Their evolution has seen these records, previously important only for the planning and coordination of care between healthcare providers, risen in importance for other stakeholders including individuals such as patients or academics, to organisations such as insurance companies, up to the governmental level. Medical records are powerful resources for these actors. They enable stakeholders to select the information required, strengthening the argument or case against the intended targets. For example, individuals may use the information for litigation purposes, while health economists may use them to influence policy. Researchers may use them for clinical trials or research and they have become a technological artefact with the potential to reform healthcare such as using data to develop algorithms to detect or manage diseases or in support of essential healthcare activities such as the exchange of clinical information to support patient-centred care.[45] As a 'repository of information',[46] medical records are a treasure-trove of facts which inevitably opens them to different functions depending on how these facts are manipulated.

As the role, importance and versatility of medical records evolve, they potentially have a wider outreach and influence in not only healthcare but to society. This form the fundamentals of the arguments in answering the question of whether Malaysia should widen patient access to medical records.

[45] Louis Raymond, Guy Pare and Marie Marchand, 'Extended Use of Electronic Health Records by Primary Care Physicians: Does the Electronic Health Record Artefact Matter?' (2017) 25 Health Informatics Journal 71.
[46] Richard S Dick, Elaine B Steen and Don E Detmer, *The Computer-Based Patient Record: A Revised Edition: An Essential Technology for Health Care.* (Revised edn, National Academy Press 1997) 131.

## 1.2 General definition

Medical records aim to provide unmediated access to the doctor's observations and thoughts. The World Health Organisation (2006) defines medical records as a collection of facts about a patient's history, including past and present illness and treatment entered by the healthcare professional who is treating the patient.[47] As the case progresses, medical records document the course of the illness and the thought process as well as the effect of medical work relating to the patient as performed during this period. In doing so, it creates not only a record but also a healthcare trajectory of the patient.

In Malaysia, the MMC has its own definition of a medical record:

> Documented information regarding the health of an identifiable individual recorded by the doctor or healthcare professional either by personal or by individual instructions. It should contain information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment.[48]

However, the MMC Guidelines distinguish medical records from medical reports. A medical report is 'a brief statement of who the practitioner is, his speciality and appointment' [49] which the doctor has the authority to write. Non-relevant content can be omitted and the written style of a healthcare provider using medical or non-medical terms is dependent on the reason for the request. In medical reports, the content provided is often implicit in nature, as the clinician may or may not disclose certain information to fit both the patient's and doctor's self-interests.

---

[47] World Health Organisation, 'Medical Records Manual: A Guide for Developing Countries' 2006) <http:www.wpro.who.int/publications/docs/MedicalRecordsManual>, accessed 11 Oct 2022.

[48] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.1.

[49] Ibid cl 2.2. The practitioner must create the report without undue delay so that it can be given to the patient within the allotted six weeks, and the Records Officer must keep a book that is duly dated and signed to attest to this. The report should only include facts, true copies that have been verified, and the findings of pertinent investigations.

On the other hand, the medical records is more comprehensive and comprises the doctors' clinical notes, nurses' reports, laboratory and imaging reports, operation and anaesthetic notes, drug prescriptions, referrals to other specialists, printouts from monitoring equipment, photographs, consent forms, computerised electronic records and records of telephone consultations related to patient care.[50] Essentially, all the patients' health-related information at the institution is coded, sectioned, centralised and made accessible to the relevant healthcare professionals.

### 1.3 The process of producing medical records

The creation of a medical record for a particular person starts with the intention to seek help from the healthcare personnel or institution. Most commonly, basic demographic details are taken to create a new record. This includes basic details such as name, date of birth, gender, ethnicity, marital status, occupation, contact details and next of kin information. A medical registration number is usually generated to identify the individual and to match to the medical record. After consultation with the health personnel, more information is recorded. Information from clinics, wards, pharmacies, the radiological department and others are all documented, creating a trove of information on the care of the individual.

### 1.4 Management of medical records

Management of medical records is a challenging process that includes determining the type of records, logistics of safekeeping and accessibility right up to the monitoring of the patient's actual health and expanded utilities including medical research, education and insurance cases,

[50] Ibid cl 1.2.

malpractice suits, medical audit and statistical studies.[51] A concerted effort is required of the health institution management, clinicians and other health practitioners to improve the standard of use, maintenance and preservation of medical records.

What information should be collected ought to be determined first as this affects how it should be stored, who will have access and the conditions to access as well as the level of dissemination allowed. It is a conglomerate of processes rather than just one step. It must capture the decisions that are made promptly in which every medical service must provide an accurate record of each encounter or setting. Medical records should be comprehensive and the omission of both relevant and non-relevant aspects of patient care should be avoided.

As a comprehensive and complete entry of a patient's healthcare journey, healthcare professionals should record every aspect of clinical care. They are shared with other healthcare professionals and are used to improve overall clinical decision-making. At the organisational level, they are also an important source for clinical audits, individually or as statistical data, which are used to improve performance. The legal system relies heavily on documentary evidence in cases of medical negligence and so medical records as a legal document should be properly written and preserved to serve the interest of both the doctor and the patient.[52] When patients decide to file a lawsuit against a doctor, medical records serve as evidence to deduce the intention and action of the doctor and of any action or inaction. It is one of the most important evidential items used in court to provide information on all aspects of patient care and to determine the quality of care provided. They are thus the most reliable and informative

[51] Amit Bali and others, 'Management of Medical Records: Facts and Figures for Surgeons' (2011) 10 Journal of Maxillofacial and Oral Surgery 199, 199.

[52] Mohammad Hossein Yarmohammadian and others, 'Medical Record Information Disclosure Laws and Policies among Selected Countries; a Comparative Study' (2010) 15 Journal of Research in Medical Sciences 140, 140.

source for both clinical and non-clinician stakeholders including patients and their legal representatives.

## 1.5 Types of records

This section discusses the formats of medical records, how these formats affect access (for both patients and healthcare professionals) and how a more readily accessible format may improve patient access to medical records. In Malaysia, medical records exists in a physical paper form with handwritten records or typed records, or in a digitalised form often known as an electronic medical record (EMR). The extent of Malaysia adopting digital medical records compared to paper records will be described in a later section (see Section 1.7)

### 1.5.1 Physical records

Physical records are those records where data may be retained that we can physically handle, with the most obvious example being paper.[53] This section highlights the advantages and disadvantages of physical paper medical records, noting the difference in natural properties that influence availability in the clinical setting but also feasibility for wider access in the current format.

Paper-based records include handwritten notes, typed reports and test results stored in a paper file system.[54] Systems for filing records allow health professionals to safely keep and quickly retrieve data. Patient-identifiable data is protected through filing systems. The kind of health information system a provider employs frequently relies on the institution's facilities, size,

[53] Crown Records Management, 'How to Store Physical Records' (2020) <https://www.crownrms.com/ae/insights/how-to-store-physical-records/>, accessed 9 June 2019.
[54] Richard Gartee, *Electronic Health Records: Understanding and Using Computerised Medical Records* (Third edn, Pearson 2016).

patient volume and how much data it maintains.[55] Inside the healthcare facility itself, paper-based records are usually kept in the medical record storage room. They are portable which allows them to be used easily at different points of care and can be easily navigated by healthcare professionals for data entry and retrieval.[56]

The characteristics of paper-based records were discussed by Barnett[57] who argued that the paper system allows for a considerable deal of flexibility in data entry and that paper records lend themselves to the unrestricted recording of subjective opinions and impressions. They let healthcare providers focus on the content, rather than the act or mechanics of recording.[58] Their characteristics allow clinicians to use the record 'on-the-move' across multiple locations within the hospital, thus helping to facilitate interactions between the actors who use them and enabling different members of staff to read, arrange and update the record during collaborative sessions.[59] The ability to position and move the physical records from a working station to a patient's bed allows easy immediate 'on the spot' access to data and information that helps in decision-making and management of the patient, which applies to both the healthcare professional and the patients themselves. These observations, although applicable to mobile hand-held devices which accommodate EMRs, allow us to observe that paper-based medical records have the quality of being 'micro-mobile'. Bardram described them in his reference to 'the way in which an artefact can be mobilised and manipulated for various purposes'.[60] Sellen and Harper described paper-based medical records specifically 'to render action visible to

---

55 Jim Molis, 'Types of Medical Record Filing Systems' 2018) <https://bizfluent.com/info-8690511-types-medical-record-filing-systems.html>, accessed 8 March 2019.

56 Abigail Sellen and Richard Harper, *The Myth of the Paperless Office* (The MIT Press, 2002).

57 Octo Barnett, 'Computers in Medicine' (1990) 263 Journal of the American Medical Association 2631, 2631-2633.

58 Ibid.

59 Jaykob Eyvind Bardram and Steven Houben, 'Collaborative Affordances of Medical Records' (2017) 27 Computer Supported Cooperative Work 1, 31.

60 Ibid 18.

others',[61] which means that the 'optic' presence of the physical properties of these types of record may highlight important changes to information or status[62]. Physical placement, orientation and manipulation are key actions that may alter the awareness of the healthcare staff regarding the care and status of the patients. Records on the ward reveal a more 'active' status or more acute case that requires attention rather than the records in the outpatient department, indicating care is scheduled and of a more non-acute or non-immediate requirement. Paper-based records are also a universally recognised format amongst healthcare professionals. Unlike electronic records, the simplicity of paper-based records does not require new users from other institutions to be trained and paper records, and unlike a computer, are not subject to downtime due to technological glitches, software updates or cyber-attack.

However, there are some disadvantages to paper-based records. The most obvious, due to being dependent on the end user, are missing data, illegible handwriting, and inconsistencies in medical note entry.[63] Secondly, availability is dependent on the efficiency of the retrieval process. Tufo et al. examined record availability, missing data and test result recording in five outpatient facilities and found that up to 30 per cent of medical records were not available during a single clinic.[64] In addition, the completeness of data is subjective. The same study also found that the quality of medical entry for general information that was important for preventive healthcare was lacking in between 43 and 70 percent of files across five hospitals.[65] Whilst this study was performed around 40 years ago and has likely improved with the advent of Hospital Information Systems (HIS), it highlights that without a proper healthcare record

---

61 Sellen and Harper, *The Myth of the Paperless Office*, 144.

62 Bardram and Houben, 'Collaborative Affordances of Medical Records', 21.

63 John F Burnum, 'The Misinformation Era: The Fall of the Medical Record' (1986) 110 Annals of Internal Medicine 482.

64 Henry M Tufo and Joseph J Speidel, 'Problems with Medical Records' (1971) 9 Medical Care 509, 512.

65 Ibid.

office responsible for tracking and retrieval, paper medical records are more vulnerable to being lost.[66]

Thirdly, Snellen and Harper[67] described the problems of paper-based records: symbolic problems, cost problems and interactional problems. Paper is a symbol of an old-fashioned organisation and moving away from it seems a more efficient and effective future. The costs of paper document systems far outweigh those of electronic systems after the point at which they have been created. Paper records may also be unwieldy as they grow with further healthcare events. A patient may end up with several volumes of information regarding their health status. Berg quoted Bleich in his work described paper records as:

> an abomination […] it is a disgrace to the profession that created it. More often than not, the chart is thick, tattered, disorganised and illegible; progress notes, consultant's notes, radiology reports and nurses' notes are all co-mingled in accession sequence. The charts confuse rather than enlighten; they provide a forbidding challenge to anyone who tries to understand what is happening to a patient.[68]

Ariffin et al. revealed that the information retrieved for hospital discharge letters was dependent on the medical record's organisation. Unlike EMRs, the traditional paper record is open to disorderliness, rendering it unsuited for the automated transfer of the information required in a comprehensive discharge letter.[69] Copies are harder to generate as information may be omitted or lost in the filing of a paper-based medical chart. To further compound matters, paper deteriorates with time,[70] which calls into question its long-term reliability.

---

66 Nik Azliza Nik Ariffin and others, 'Implementation of Electronic Medical Records in Developing Countries: Challenges & Barriers' (2018) 7 International Journal of Academic Research in Progressive Education and Development 187.

67 Sellen and Harper, *The Myth of the Paperless Office*.

68 Marc Berg and Geoffrey Bowker, ' The Multiple Bodies of the Medical Record: Toward a Sociology of an Artifact' (1997) 38 The Sociological Quarterly 513, 523.

69 Nik Ariffin and others, 'Implementation of Electronic Medical Records in Developing Countries: Challenges & Barriers', 189.

70 The George Washington University, 'The Difference between Electronic and Paper Documents ' <https://www2.seas.gwu.edu/~shmuel/WORK/Differences/Chapter%203%20-%20Sources.pdf>, accessed 25 June 2019.

Storage of paper-based medical records has also become one of the most compelling reasons to adopt electronic records. Under the MoH in Malaysia, paper-based medical records must be held for 7 years after the last treatment date before disposal is permitted.[71] Paediatric and obstetric medical records must be kept for 21 years and psychiatric medical records can only be disposed of 3 years after the patient's death.[72] Significant storage requirements and the inability to transfer point-of-care information to clinicians and the disadvantages outlined above have compelled many healthcare systems to move towards electronic records.

These points show the need to improve access, pointing to a new modality over traditional paper-based physical records. Improvements in technology suggest an answer to these drawbacks by migrating to digital records, particularly the use of EMR (see Section 1.7.2).

### 1.5.2 Electronic records

Digitalisation sees the conversion of information into a digital or computerised form either directly into a prepared interface such as an EMR or from the conversion of traditional paper records into a digital form by scanning and uploading. The former is a commonly used method, with the latter as a transitional tool from physical to digitalised records.

Electronic records are computerised medical records that are composed of clinical data repositories, clinical decisions, order entries and drug prescriptions.[73] The EMR is a computerised version of the patient's medical record that can be accessed anywhere within the healthcare institution.[74] Information in the EMR includes the patient's demographics, medical

---

[71] Ministry of Health, *Jadual Pelupusan Rekod Perubatan Kementerian Kesihatan Malaysia* (2007) 7.
[72] Ibid 17-21.
[73] Nur Izzatty Ismail and Nor Hazana Abdullah, 'Developing Electronic Medical Records Framework for Malaysia's Public Hospitals' (IEEE Colloquium on Humanities, Science and Engineering).
[74] Nik Ariffin and others, 'Implementation of Electronic Medical Records in Developing Countries: Challenges & Barriers', 189.

history, diagnosis, medication list, laboratory or radiology results and procedures and interventions undertaken and are restricted to authorised personnel only.

Electronic health records (EHR) are a collection of EMRs captured in digital format which can be exchanged across healthcare settings by being incorporated into the network information system.[75] It is more comprehensive and may include other tools such as electronic laboratory orders and electronic prescribing. The EHR allows different aspects of medical practice to be performed on a single interface. The availability of all these functions and their standardisation allows proper and effective communications between separate practices, be they interdepartmental, inter-hospitals or inter-health services.

## 1.6 Comparison of digitalised and physical records

Electronic records systems eliminate the drawbacks of manual record systems such as poor and illegible handwriting.[76] A benefit of EMR is improving consistency and ensuring standardisation of clinical notes by using a standard template and drop menus which ensure that mandatory information such as date and time are recorded and cannot be changed. Secondly, what previously was subjective opinion is standardised by the use of classifications and drop-down menus. For example, ‘severe’ gastritis to physician A might be ‘moderate’ gastritis to physician B. The use of predefined classifications in drop-down menus ensures that physician B understands what is meant by ‘severe’ by physician A. Hence, the use of EMR avoids many of the drawbacks of paper-based records and ensures standardisation of the patient’s records.

---

[75] World Health Organisation, 'Medical Records Manual: A Guide for Developing Countries', 102.

[76] Nir Menachemi and Taleah H Collum, 'Benefits and Drawbacks of Electronic Health Record Systems' (2011) 4 Risk Management and Healthcare Policy 47, 48.

### 1.6.1 Advantages of electronic records

Electronic medical records provide a range of benefits for patient empowerment, particularly that they can be made easily available, and are thus potentially valuable to both doctors and patients. The standardisation of electronic records gives the healthcare provider a more detailed description of the patient's health status. They improve communication between physicians and patients after referral to other physicians as the data are more consistent and accessible.[77] They act as a safety net in reducing medical errors and promoting effective clinical management. These include potential risks such as previous cardiovascular events, multi-drug resistant infections and drug allergies.[78] A physician seeing the patient for the first time would know to avoid potentially adverse medications as they can be highlighted on the EMR. From a safety perspective, interactive prompt capacity can be integrated which automatically highlights important safety information.[79] Such programmes serve to remind clinicians of the presence of guidelines or possible drug interactions and the necessity for additional observation or amendment of the rules for the case at hand. Previous medical history is quickly accessible, coupled with the standardisation of subjective opinions which also allows patients to be triaged more appropriately to the level of urgency required.

Electronic record systems' multiple access functions considerably improve the efficiency of information transmission and exchange between professionals and facilitate access to patient data.[80] The use of electronic records supports mobile and concurrent work as the patient's records are accessible from computers all over the hospital and allow simultaneous access to

[77] Adol Esquivel and others, 'Improving the Effectiveness of Electronic Health Record-Based Referral Processes' (2012) 12 BMC Medical Informatics and Decision Making , 1.
[78] Bakheet Aldosari, 'Patients' Safety in the Era of EMR/EHR Automation' (2017) 9 Informatics in Medicine Unlocked 230.
[79] Clemens Scott Kruse and others, 'Security Techniques for the Electronic Health Records' (2017) 41 Journal of Medical System 1, 5.
[80] Menachemi and Collum, 'Benefits and Drawbacks of Electronic Health Record Systems', 48.

patient data. As a result, electronic records can improve information sharing among caregivers without requiring them to meet.[81] This was particularly evident during the Covid-19 pandemic when a dedicated network of specialist services in different institutions under one health trust (or health governing board) could meet virtually using the same electronic records for complex patients.[82] It can also improve the efficiency of the working process, as an order can be made at any point of care rather than having to physically engage with and submit physical forms to the relevant department.

Many healthcare institutions have invested in health information systems to improve how medical records are managed, modified and made available for use most practically and cost-effectively.[83] EMRs have many advantages including easier access to patient data tempo-spatially, improved administrative coordination, data entry and updates as well as space-saving[84] in addition to upholding patient privacy, confidentiality and protection. EMRs have a security policy that acts as a reference to anybody who has access to the system, including patients and medical professionals. Access restrictions, firewalls and data encryption technologies are a few protections that improve the security of healthcare data.[85] Electronic records can exchange health information immediately and with greater security which helps healthcare organisations provide integrated higher quality, consistent and safer care for patients whilst promoting standardisation of practice across professional boundaries.[86] For example, there is often a disconnect between the care provided in the hospital and the community. Accessible electronic records allow hospital clinicians, general practitioners and the

[81] RS Evans, 'Electronic Health Records: Then, Now, and in the Future' (2016) 1 Yearbook of Medical Informatics 48.
[82] International Labour Organization, *Teleworking During the Covid-19 Pandemic and Beyond: A Practical Guide*, (2020).
[83] Evans, 'Electronic Health Records: Then, Now, and in the Future'.
[84] Kruse and others, 'Security Techniques for the Electronic Health Records', 2.
[85] Ibid 5.
[86] Menachemi and Collum, 'Benefits and Drawbacks of Electronic Health Record Systems', 47.

multidisciplinary team in hospitals as well as the community to ensure continuity of care and integrate care plans with a multidisciplinary approach through a system of information exchange which is created to provide a means for professionals to transmit information to others instantaneously. The fast and efficient transmission of records improves treatment efficacy and reduces delays, which ultimately leads to benefits for patients. For example, in intensive care units, an urgent communication between different clinical specialties may save a patient's life. EMR also allows better transitioning between care in acute hospitals and in the community, facilitating improved patient-centred care. Campanella et al.[87] suggested that, when implemented correctly, electronic records systems can enhance healthcare quality by boosting productivity, promoting adherence to recommendations and lowering prescription mistakes and adverse drug events. Therefore, it is important to advocate for and support these implementation strategies.[88] The benefits have also been recognised by the American Medical Association (AMA) which advocates the greater adoption of EMR to foster improved treatment, public health, patient safety, quality improvement, medical liability defence and research.[89]

Another advantage is that it is always available. It has failsafe backup systems such as external data storage that ensures information is never lost, even during a system shutdown. Coding in electronic records also allows programmes to be constructed in such a way that information relevant to a particular service can be identified in, for example, audit, quality assurance and research.

[87] Paolo Campanella and others, 'The Impact of Electronic Health Records on Healthcare Quality: A Systematic Review and Meta-Analysis' (2015) 26 European Journal of Public Health 60.
[88] Ibid.
[89] American Medical Association, 'Guiding Principles for the Collection, Use, and Warehousing of Eelectronic Medical Records and Claims Data' <www.ama-assn.org/apps/pf_new/pf_online>, accessed 20 November 2019.

Another significant advantage is that it reduces patient waiting times, which are often described as one of the major challenges and performance indicators in hospital management.[90] Medical records and information are readily available at a click of a button rather than having to wait for the physical records, therefore reducing waiting time. Investigations with pending results are easily retrieved, further reducing waiting time. A good EHR system can even indicate when a particular test result will be available, inarguably useful in arranging and planning patient appointments and reviews.

It also provides an advantage for administrative efficiency as electronic information systems are a good platform for discharge planning, facilitating early discharge and even reducing the length of stay by permitting timely radiology reporting and immediate access to investigation reports. Therefore, patients may be discharged earlier and there is greater flexibility in follow-up appointment scheduling. Accessibility of these types of information to non-medical professionals such as auditors, coders and policymakers allows improvements to be made to the overall system.

The UK is a prime example in which health records are part of the national EHR system and include non-medical professionals.[91] The Department of Health has incorporated web-based access which allows National Health Service (NHS) staff involved directly or indirectly in patient care to have access to patients' confidential records to improve overall care. This includes non-clinical staff such as administrative workers, secretaries, clinical coders, quality and risk officers as well as registry officers.[92]

---

[90] Abdulrahman Jabour, 'The Impact of Electronic Health Records on the Duration of Patients' Visits: Time and Motion Study' (2020) 8 Journal of Medical Internet Research Medical Informatics .

[91] Giovanni Rinaldi, *New Perspectives in Medical Records: Meeting the Needs of Patients and Practitioners (Tele-Health)* (Springer 2017).

[92] The Scotsman, 'Patient Records 'Open to Prying Eyes'' (2010) <https://www.scotsman.com/health/patient-records-open-prying-eyes-2471207>, accessed 5 July 2022.

Also relevant to the central argument of this thesis is that electronic record systems allow patients easier access to their own medical information compared to paper-based records as this is usually the platform in which direct access to patients is granted.[93] EMR offers a spectrum of benefits when it comes to the empowerment of patients, especially if readily accessible, and is therefore potentially beneficial to both doctors and patients. EMR has also enabled healthcare systems to facilitate improvements in the quality and communication of medical care. [94] For example, 70% of primary physicians in the US use EMR systems[95] and this has been shown to improve the continuity of care for patients and give them greater access and responsibility over their health records. A study of the use of web-based assessment for patients has shown that 70% of doctors reported improved trust, better doctor-patient relationships and enhanced decision-making.[96] It is the positive aspect of improving patient satisfaction and related outcomes and being the most usable real-time platform to access data for different stakeholders including patients that has compelled many healthcare systems to adopt this digitalised format of recording patients' medical information.

### 1.6.2 Disadvantages of electronic records

There are, however, disadvantages to the EMR system. First, it is expensive as the high initial costs include setup, additional hardware, maintenance, and training costs.[97] Like any electronic technology, system interoperability may cause malfunctions in data integration. It is also unclear whether doctors will embrace the changes of recognised barriers including a lack of

---

[93] American Medical Association, 'Guiding Principles for the Collection, Use, and Warehousing of Eelectronic Medical Records and Claims Data'.

[94] Walter F Stewart and others, 'Bridging the Inferential Gap: The Electronic Health Record and Clinical Evidence' (2007) 26 Health Affairs , 181-182.

[95] Sherry Liou, 'Electronic Medical Records: The Good and the Bad' (2014) 7 Quill & Scope 14, 14.

[96] Brian McMillan and others, 'Primary Care Patient Records in the United Kingdom: Past, Present, and Future Research Priorities' (2018) 20 Journal of Medical Internet Research , 4.

[97] DA Ludwick and John Doucette, 'Primary Care Physicians' Experience with Electronic Medical Records: Barriers to Implementation in a Fee-for- Service Environment' (2009) International Journal of Telemedicine and Applications 1.

faith in new technologies, bad experiences with electronic health records, and fear of the pace of change.[98] Another problem is the issue of confidentiality which may arise when the EMR programme becomes wrongly accessible to an unauthorised person, enabling access to private information. In a survey of 5,000 participants, 79% of patients and members of the public were concerned about the security risk and the potential threat to the confidentiality of their EMR.[99]

Other institutional risks relating to EMR include software failure, virus threats and cyber-attack threats. Other issues with EMR include longer handling times, a lack of standards and privacy hazards.[100] For instance, in 2017, a cyber-attack dubbed WannaCry revealed the weaknesses of the NHS. There were effects on more than 60 NHS trusts and numerous medical facilities[101] with many healthcare facilities not able to access patient records which led to delays on non-urgent surgeries and cancelled appointments. The NHS was criticised because its system was vulnerable as its Microsoft Windows operating systems were more than 15 years old and no longer updated or supported by Microsoft, particularly concerning virus threats.[102] We can however argue that these risks originated from institutional governance as opposed to the failure of EMR as a tool.

There are other limitations to electronic records. A recent study by Mayo Clinic researchers[103] and the AMA, discovered that more than half of physicians felt emotionally exhausted by the

---

98 Lauren Vogel, 'Doctors Need Retraining to Keep up with Technological Change' (2018) 190 Canadian Medical Association Journal , 90.

99 Chrysanthi Papoutsi and others, 'Patient and Public Views About the Security and Privacy of Electronic Health Records (EHRs) in the Uk: Results from a Mixed Methods Study' (2015) 15 BMC Medical Informatics and Decision Making 1, 10.

100 WR Hersh, 'The Electronic Medical Record: Promises and Problems.' (1995) 46 The Journal of the American Society for Information Science 772, 775.

101 William Smart, 'Lessons Learned Review of the Wannacry Ransomware Cyber Attack' (2018) <https://www.england.nhs.uk/wp-content/uploads/2018/02/lessons-learned-review-wannacry-ransomware-cyber-attack-cio-review.pdf>, accessed 6 January 2020.

102 Ibid.

103 American Medical Association, 'Guiding Principles for the Collection, Use, and Warehousing of Eelectronic Medical Records and Claims Data'; Christopher Jason, 'Ama Study Shows Poor EHR Usability Leads to Physician Burnout' (2019) <https://ehrintelligence.com/news/ama-study-shows-poor-ehr-usability-leads-to-physician-burnout>, accessed 24 January 2020.

use of EMR. Heavier workloads and 'increased clerical responsibilities'[104] were among the chief complaints. A recent paper reported that adopting a new EHR system doubled the cognitive workload on staff and persisted for at least 30 months.[105] The authors claimed that EMR turned routine tasks into a protracted multi-step process, decreasing efficiency and forcing clinicians to devote off-duty hours to entering data from patient visits. Physicians also need time to train and become literate with the technology.[106] Griffith et al. [107] demonstrated that at Birmingham's Dudley Road Hospital, handwritten notes were preferred over computer printouts by all therapists as they were less time-consuming. Doctors observed that thinking about and writing their own notes helped them 'crystallise' their ideas. In this institution, handwritten notes were determined to be more concise.[108] The researcher also referenced studies that claimed the use of computers to document patient information could negatively alter the way people relate to doctors, [109] probably due to the time spent on technology as opposed to patients during a consultation.

Researchers from the Research and Development (RAND) Corporation, a global policy think tank, interviewed physicians who reported that electronic record technology had significantly worsened professional satisfaction in multiple ways.[110] According to the report, aspects of current electronic records that were particularly common sources of dissatisfaction included poor usability, time-consuming data entry, interference with face-to-face patient care, inefficiency and less fulfilling work content, inability to exchange health information and

---

[104] Jason, 'Ama Study Shows Poor EHR Usability Leads to Physician Burnout'

[105] Karen Dunn Lopez and others, 'Electronic Health Record Usability and Workload Changes over Time for Provider and Nursing Staff Following Transition to New EHR' (2021) 93 Applied Ergonomics 1, 6.

[106] Ismail and Abdullah, 'Developing Electronic Medical Records Framework for Malaysia's Public Hospitals', 340.

[107] Sian Griffiths, 'Evaluating Health Care Record in Rheumatology', University of Sheffield (1996).

[108] Ibid.

[109] Ibid.

[110] Mark W Friedberg and others, *Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy* (Rand Health Quarterly, (2013) 17.

degradation of clinical documentation.[111] Comprehensive drop-down menus in electronic record systems that may or may not be relevant to the patient may render positive findings less significant to a clinical and logical conclusion as the clinicians lose focus due to the amount of information required to fill in the electronic forms. Therefore, the purpose and functionality of this technology may affect traditional styles of medical entry that are usually concise and focused on the problem. For example, a simple presentation of acute appendicitis in a 19-year-old male who is independent in all activities of daily function needing surgical treatment requires a 'social history' such as occupation or living condition. Such data are less relevant but still required by the electronic record before allowing the clinician to continue to the next section of the clinical entry. Therefore, the type and format of information may differ in importance; however, electronic records are inflexible for medical practitioners to 'cherry pick' the most relevant entry pertaining to the current care that is being provided.

## 1.7 Introduction of hospital information system in Malaysia

Previously, I have elaborated on how EMR facilitates access to medical records. These characteristics and the advantages and disadvantages of information retrieval feed into the central argument on how EMR can improve the overall accessibility to medical records. As EMR is an important tool for healthcare with overall benefits, it is likely to be adopted and used for a long time. Although the introduction of EMR has improved the overall accessibility of medical records systems in several hospitals in Malaysia, this has not been fully implemented nationwide.[112] In this section, I will explain how and why the Hospital

[111] Ibid 111.

[112] Ismail and Abdullah, 'Developing Electronic Medical Records Framework for Malaysia's Public Hospitals'.

Information System (HIS) in Malaysia was established and its significance from a patient access point of view.

The Malaysian healthcare system under the MoH is the main provider of healthcare through public hospitals, general practitioners and private healthcare facilities.[113] The Malaysian Government has established several projects to promote and preserve the well-being of the Malaysian people by providing greater access to healthcare knowledge through education, training and awareness programmes.[114]

The development of a Total Hospital Information System (THIS) seeks to provide an integrated care delivery network capable of exchanging information, automating work processes, providing greater performance and improving data storage and use for specific medical, statistical or research purposes. THIS also seeks to provide easy access to data sharing between providers while improving patient safety in disease management, providing better record keeping and protection as well as improving workflow through work process.[115] Other functions of THIS include patient appointments and scheduling, patient registration, admission, discharge and transfer and managing the documentation of clinical data. It was developed to order investigations, prescribe medications, enter clinical and test reports and manage specialty referrals and clinical outcomes.[116] Central to this is advancing e-health initiatives by adding THIS under the government's Vision 2020 plan.[117] This healthcare reform initiative is an outcome of the telehealth project Multimedia Super Corridor that was launched in 1997. Since

[113] BJJ Abdullah, 'Impact of Teleradiology in Clinical Practice: A Malaysian Perspective' in Sajesh Kumar and Elizabeth Krupinski (eds), *Teleradiology* (Springer 2008) 205.
[114] Hidayah Sulaiman, 'Healthcare Information Systems Assimilation: The Malaysian Experience', RMIT University (2011).
[115] Abdullah, 'Impact of Teleradiology in Clinical Practice: A Malaysian Perspective', 204.
[116] Sulaiman, 'Healthcare Information Systems Assimilation: The Malaysian Experience'.
[117] Jai Mohan and Razali Raja Yaacob, 'The Malaysian Telehealth Flagship Application: A National Approach to Health Data Protection and Utilisation and Consumer Rights' (2004) 73 International Journal of Medical Informatics 217, 217.

the launch of the project, 3,616 public health facilities comprising 135 public hospitals, of which 18 are tertiary referral hospitals that include a fully or partially integrated HIS.[118]

### 1.7.1 EMR's role in patient access

As part of the 12th Malaysia Plan which was introduced in Parliament in 2006, the government has executed the EMR plan in phases. Individuals' lifetime health records have been digitised and made available across health facilities using EMR. The initiative focuses on digitalising healthcare and includes the creation of a new research centre at the National Institute of Health to speed the development of innovative digital healthcare products and services. Dr Adham Baba, the previous Health Minister, said in Parliament in July 2020 that 37 of 146 government hospitals (25%) and 97 of 1,090 public health clinics (9%) were already employing an EMR system. He also said that a health information exchange platform called MyHix was being used by ten hospitals and a public health clinic to share digital records. Adham also reported on Phase One of the National EMR Project in which seven hospitals, 44 public health clinics and 12 dental clinics were participating, and which included online patient registration and appointments, electronic payments and virtual consultations for a fully integrated end-to-end EMR system.[119]

In Malaysia, access to EMR is restricted to healthcare providers to protect the privacy of the patient and to preserve trust between doctors and patients due to the obligation of confidentiality. The healthcare system in Malaysia has been praised as of high standards, including the integration of digital infrastructure.[120] Malaysia is committed to further developing its digital healthcare due to its overwhelming benefits including improved accessibility, better healthcare institutional integration and the provision of big data for

[118] Ministry of Health Malaysia, *Ministry of Health Official Website* (2010).
[119] Ministry of Health, *Electronic Medical Records* (2006).
[120] Sulaiman, 'Healthcare Information Systems Assimilation: The Malaysian Experience'.

research purposes. Although in one aspect – direct patient access to medical records – remains a foreign concept, the commitment and investment in digital healthcare coupled with increasing health awareness and literacy will eventually lead to patient access.

The introduction of EMR has undeniably improved medical records access for healthcare personnel, while providing better transparency and governance of medical records, particularly in the current healthcare landscape of cross-specialty referrals and multidisciplinary healthcare. Nevertheless, it has not universally improved patient access or the dialogue on patient access to their own medical records. Despite not being a main goal of policymakers to use EMR for patients nor to automatically improve patient access, the system from a technological perspective does make access for patients easier in the future. Therefore, it is imperative to emphasise here that it is not technological limitations in Malaysia that have hampered the progress towards improving patient access. Malaysia has already acknowledged and introduced EMR in some of the hospitals. The main obstacle is the lack of awareness, even at the policy-making level, resulting in the lack of rights in legislation. The decisions to use technology and enhance rights should be universal as the technology itself is neutral.[121]

Although Malaysia has started adopting EMR in practice and indeed EMR has been shown to improve access as seen in many other countries,[122] it remains futile for patient access if the basic tenet to define the rights of patients is not firstly ascertained. However, EMR as a technology remains an important key for regulatory reform to improve patient access to medical records as will be discussed later in this thesis.

---

[121] Paul Henman, 'Computer Technology - a Political Player in Social Policy Processes' (1997) 26 Journal of Social Policy 323, 324.

[122] Faustine Williams and Suanne Austin Boren, 'The Role of the Electronic Medical Record (EMR) in Care Delivery Development in Developing Countries: A Systematic Review' (2008) 16 The Journal of Innovation in Health Informatics , 139.

Before justifying and proposing strategies to widen access, there is a need to recognise the normative function of medical records as a documentation tool and its other undifferentiated roles. This will highlight their potential usefulness as a multi-purpose tool because it has a social and political effect at many levels. The majority of hospitals in Malaysia are still using paper-based records and the fragmentation of the healthcare system (see Chapter 2) will hinder access to medical records for many stakeholders including patients. In institutions where EMR has been successfully introduced, the system is still restricted to healthcare providers as access is limited to both protect the privacy of the patient and the autonomy of doctors.

### 1.7.2 Current Digital Technology and Aspects of Patient Use of Health Records

Despite the deployment of electronic records, paper medical records are still widely used. In Malaysia, 70% of the public hospitals are still reported as using paper records.[123] Due to the technological nature of electronic medical records, providing patient access using electronic records has a timely and immediate impact on patient care as information is accessible in real time.[124] According to research, a growing number of patients, including 80% of the 28 million users of the NHS App in the UK, demand quick access to health information for themselves.[125]

A software programme enables users to examine their own health information and to access a summary of clinical information, allowing timely and real-time transfer of information.[126] Electronic records help doctors and the multidisciplinary team to communicate and interact better. Templates for consultation letters, medical notes and chart summaries provide consultants and other team members with readable, structured information. Because of the clear

[123] Ministry of Health, *Electronic Medical Records*.

[124] Abdullah, 'Impact of Teleradiology in Clinical Practice: A Malaysian Perspective'.

[125] National Health Service, 'Access to Patient Records through the NHS App' (*National Health Service,* 2022) <https://transform.england.nhs.uk/information-governance/guidance/access-to-patient-records-through-the-nhs-app/>, accessed 7 July 2023.

[126] Nidhi Bouri and Sanjana Ravi, 'Going Mobile: How Mobile Personal Health Records Can Improve Health Care During Emergencies' (2014) 2 JMIR mHealth and uHealth .

and organised nature of the prescriptions, there are fewer medical errors during clinical entry.[127]

According to certain studies, technology can help people to acquire information more easily and more efficiently.[128] According to Winkelman et al., patients who are interested in their own health data are typically motivated to take greater control of their condition's care and management.[129] The impact of technological advancements on patient-physician interactions enables patients to spot any faults in the electronic record and enhance data quality, which may prevent medical errors.[130] More accurate health information results from this[131] and it will enhance communication.[132] It also affects the maintenance and promotion of health. Convenient access to an electronic health portal could, in and of itself, have a major positive impact on health.[133]

Since November 2022, the majority of patients in the UK, mainly in England, who have online accounts (through the NHS App or other patient online apps) will automatically be able to view new entries in their clinical record, including information about their medication, test results, and records of appointments with any clinician entering information into the clinical system.[134] Primary care EHR providers enable patients with safe and secure access to their health records

---

127 Canadian Health Infoway, *The Emerging Benefits of Electronic Medical Record Use in Community-Based Care*, (2013).

128 Harold Thimbleby, 'Technology and the Future of Healthcare' (2013) 2 Journal of Public Health Research 160, 162.

129 Warren J Winkelman and Peter G Rossos, 'Patient-Perceived Usefulness of Online Electronic Medical Records: Employing Grounded Theory in the Development of Information and Communication Technologies for Use by Patients Living with Chronic Illness' (2005) 12 Journal of the American Medical Informatics Association 306.

130 Stephen E Ross and Chen Tan Lin, 'The Effects of Promoting Patient Access to Medical Records: A Review' (2003) 10 Journal of the American Medical Informatics Association .

131 Ibid.

132 Ana Ferreira and others, 'Why Facilitate Patient Access to Medical Records' (2007) Studies in Health Technology and Informatics 77.

133 Abrar Altukistani and others, 'Patient Portal Functionalities and Patient Outcomes among Patients with Diabetes: Systematic Review' (2020) 22 Journal of Medical Internet Research .

134 National Health Service, 'Access to Patient Records through the NHS App'.

through readily available tools, systems, or applications like Care Information Exchange[135] (targeting users in North West London NHS trusts) and MyCareUCLH[136] (a digital portal for University College London Hospitals patients). The Care Information Exchange's objective is to guarantee that patients can safely access their medical records online through a web application supplied by a social enterprise company known as Patients Know Best.[137] Another technology, SystmOnline[138], accessible through a recently released NHS App allows patients to examine their electronic medical data in addition to offering other functions like appointment management or repeat prescriptions. Its goal is to implement the 'one patient, one record' approach, which enables access to share patient records across all healthcare facilities to any staff member who requires it for patient care. If a user is already registered with SystmOne, they can access a patient's previous record, allowing them to retrieve and record previous information without having to start over from scratch. Users have access to Personal Demographic Service and GP Connect capabilities, which allows users to retrieve patient demographics from other systems for patients who are not yet registered on SystmOne. This functionality speeds up the registration process for patients who are not yet on SystmOne; if a patient is already registered, all data from the process including essential immunisation information are entered into their existing electronic health record. This guarantees that their future interactions with medical providers will provide continuity of care.[139]

Other reported benefits include a more active role in controlling their own health for patients who have better access to health information.[140] The number of patients who prefer limited or

---

135 Care Information Exchange, 'How It Works' <https://www.careinformationexchange-nwl.nhs.uk/how-it-works>, accessed 10 June 2023.

136 National Health Service University College London Hospitals, 'Mycare UCLH' <https://www.uclh.nhs.uk/our-services/find-service/mycare-uclh>, accessed 8 June 2023.

137 Care Information Exchange, 'How It Works'.

138 National Health Service, 'TPP (Systmone Hub)', accessed 8 June 2023.

139 Ibid.

140 *Canadian Health Infoway, The Emerging Benefits of Electronic Medical Record Use in Community-Based Care.*

restricted access to their records far outweighs the number of patients who have expressed a desire to view their records.[141] Automatic shared access of this information will lessen the burden on GPs over the long term and reduce manual sharing upon individual patient requests. Better access to records supports a patient-centric approach to health and treatment, enabling individuals to better understand and manage their own health, which improves health outcomes as well as patient and staff satisfaction.[142]

There are, however, concerns regarding the process of rolling out patient access using electronic medical records. The NHS has a poor record when it comes to wide-scale adoption of digital technology. In 1992, for instance, the National Programme for IT and the National Information Technology Strategy for the NHS both failed to connect primary and secondary care IT systems and to develop a single electronic health record system. They received criticism for being overly centralised and not understanding users' needs.[143] According to David Wrigley, the deputy chair of the BMA's GP Committee, many GP practices fear they are not safely ready to roll out patient records or addressing issues arising from patient access.[144] Loss of privacy of medical information is also one of the main concerns, especially for vulnerable patients who have mental health issues or cognitive impairment.[145]

Ethical considerations inherently arise in line with aspects related to patient access as will be discussed later in the thesis. Digital health and technology also have ethical implications in the form of 'digital justice', that is, the equitable and fair distribution of digital technologies and their benefits within society. It is relatable to 'health and fairness' when balancing the benefits

---

141 National Health Service, 'Access to Patient Records through the NHS App'.

142 Ibid.

143 Matthew Limb, 'Patient Access to Medical Records: What Is Happening with the Rollout in England?' (2022) 379 British Medical Journal 2.

144 David Wrigley, 'Call to Rethink Citizen Access Programme' (*British Medical Association,* 2022) <https://www.bma.org.uk/news-and-opinion/call-to-rethink-citizen-access-programme>, accessed 27 February 2023.

145 Ibid.

and risks of population health interventions.[146] This principle sustains when people of different socioeconomic classes, ethnicity, age, or gender, are not provided with equal health care services and information sources[147] However, digital justice is essential in ensuring that everyone has access to healthcare information, regardless of their background or level of technological proficiency. As the issues specifically centre around equitable access to digital health services in terms of affordability of and access to technological equipment, there are certain populations who have limited knowledge of such technologies due to age, education and socioeconomic background The most significant hurdle faced in the implementation of e-health and EMR is the fair distribution of resources, as many people still do not have access to the mandatory equipment, internet, and knowledge to understand the technology.[148] For example, patients without smartphones or computers may face difficulties in retrieving their medical records online. This may include older adults, low-income communities and rural populations. Therefore, by enabling people to take control of their health information and encouraging fair access to healthcare services, the use of electronic medical records remains the most feasible and cost-effective form for patient access to medical records; however, the service must be based on patient-centred care and bring together the socio-digital divide with adequate resources and education.

[146] Caroline Brall, Peter Schroder Back and Els Maeckelberghe, 'Ethical Aspects of Digital Health from a Justice Point of View' (2019) 29 European Journal of Public Health 18, 18.
[147] Elizabeth J Layman, 'Ethical Issues and the Electronic Health Record' (2020) 39 Health Care Management 150.
[148] Sara Pinto and others, 'Healthcare Technologies: An Ethical Discussion' (2018) 24 Britiah Journal of Healthcare Management .

## 1.8 Social significance of medical records

Medical records were designed to document medical history, management plans, ensuring continuity of care and communication amongst healthcare professionals on patient care. While this remains their primary function, it has grown to serve a variety of expanded secondary roles which influence society, including medical education, clinical audits, research and tools for quality assurance such as epidemiological surveillance. They also serve as significant legal protection like a standalone document; an accountable tool that explains the relationship and decision between, for example, patients and clinicians.[149]

Their acquired significance for social systems includes the domains of law and medicine. For healthcare professionals, the direct significance is to diagnose and treat; for legal professionals, their concerns are in establishing and proving a legal claim. Hence, the multidimensional roles of medical records as underpinned by this wider social significance are because they are a repository of data and a properly documented history that is reliably generated over time. They expand to include different aspects of an individual's demographics, behaviour and actions leading to different health outcomes and knowledge. For example, after a stroke, the physician will explore and document in the records the causative factors, family history and social adaptability to care and rehabilitation.

Medical records have increased social significance to healthcare leaders, historical researchers, social and legal scholars, economic analysts, insurance underwriters and policymakers. We can better understand the role that medical records play in society by looking at how they are used in different fields and why they are relevant to the work of many different types of social actors. The application of the data analysed undoubtedly influences the need to replace and increase insurance coverage or even healthcare budget allocation, based on the evolving pattern of

[149] Judy H Bernhardt, 'Record Keeping - Key to Professional Accountability' (1978) 26 Occupational Health Nursing 22, 28.

healthcare priorities. For example, until the recent Covid-19 pandemic, the shift of healthcare utilisation in the 20th century was away from the communicable diseases, which were declining due to effective antibiotics, towards non-communicable diseases such as heart disease, lung disease, obesity and stroke. [150]

The relevance of medical records continues to broaden and evolve, especially with the development of computer technology and its use in managing medical records. Manual medical records have transformed and moved from opportunistic records to integrated medical records that were maintained from birth to death. The move towards digitalisation has continued by becoming an integral all-encompassing modern tool on health that documents not only health, but health-related status such as the economic and social factors that directly and indirectly contribute to healthcare outcomes.

While earlier I identify each type of medical records and their forms and functions, I would like to further discuss the conceptual roles of health documentation as a large apparatus significant to the legal, moral and political health systems in society, used dynamically and configured around the goals and values of both doctors and patients as well as the community. Medical records have become a way for authorities to facilitate patient empowerment, technological self-care, improvement of health research, service planning and the reconfiguration of health provision due to the accessibility of wealth and new data knowledge. This is significant socially as medical records serve as the basis for realising patients' rights both in civil, legal and ethical transactions.

Foucault's work on government marks a new way of thinking about these issues for ethics in which technology or tools may evolve.[151] Ethics is interpreted as habitual behaviour in which

[150] M. Reza Azarpazhooh and others, 'Covid-19 Pandemic and Burden of Non-Communicable Diseases: An Ecological Study on Data of 185 Countries' (2020) 29 Journal Stroke Cerebrovascular Disease .

[151] Lenka Ucnik, 'Ethics, Politics and the Transformative Possibilities of the Self in Hannah Arendt and Michel Foucault' (2018) 44 Philosophy and Social Criticism 200, 200.

people learn to comprehend and act on themselves within specific regimes of authority (such as the law) and knowledge as well as using specific self-improvement strategies. [152] The evolution of medical records as a multidimensional tool developed inherently from various self-interests of many stakeholders, such as primary clinicians, researchers or hospital auditors, who used these tools for different reasons.

As a technology of power in society that has the effect of creating authorities, I will also discuss medical records as an 'art of government' with the physical properties and wealth of information providing a basis for assorted tasks 'to know and govern the information' and to improve the health and happiness of populations. [153] This concept was described initially by Foucault who suggested that the 'governmentalisation' of the state was linked to a whole range of apparatus of the government to rationalise necessary social and economic functions, including health.[154] He proposed that the idea of 'government' is not only limited to state politics but also a non-state political form of power based on a complex body of knowledge and 'know-how' packed into rationalities of governing, which subsequently distribute the political power within society using an assemblage of persons, theories and technologies.[155] Thus, political power is used in a variety of ways through various organisations, social groups and strategies that may only be tangentially related to the formal bureaucracy of the state. Medical records, for example, are these readily available 'inscriptions' that can be used for 'arrogation and exercise of power'.[156]

---

[152] Nikolas Rose, Pat O'Malley and Mariana Valverde, 'Governmentality' (2006) 2 Annual Review of Law and Social Science 83, 90.

[153] Steve Matthewman, 'Michel Foucault, Technology, and Actor-Network Theory' (2013) 17 Society for Philosophy and Technology Quarterly Electronic Journal 274, 276.

[154] Ibid 276.

[155] Joshua S Yang, Hadii M Mamudu and Timothy K Mackey, 'Governing Noncommunicable Diseases through Political Rationality and Technologies of Government: A Discourse Analysis' (2020) 17 International Journal of Environmental Research and Public Health , 5.

[156] Berg and Bowker, ' The Multiple Bodies of the Medical Record: Toward a Sociology of an Artifact', 533.

I relate this concept to medical records in which the medical professionals 'in the know' have the power to confer, compile and control information added into these records which then flow into or to another agent who may 'determine the inscriptions, accumulates them, contemplates them in their aggregated form and hence can compare and evaluate the activities of others who are merely entries on the chart'.[157] Rose and Miller's work examined this concept of government which emphasises the complex and variegated procedures whereby autonomous individuals or groups and their actions are brought in line with a specific outcome.[158] Medical records provide a guaranteed wealth of data that continues to grow. Therefore, the concept of governmentality applies whereby the governance of medical records and their utility is regulated from the inside by autonomous healthcare professionals and their institutions to create an expanding and shifting knowledge about a particular status in the health of the individual and the population. As medical records not only contain data and information but can also be organised, analysed, coded and measured, they facilitate the application of power because they can be used to govern at a distance. The government has the power to involve the application of data from medical records into physical force onto others. The governmentality thesis avoids seeing power in these fixed terms and acknowledges that power morphs into different forms, such as bodies of knowledge that govern people's behaviour and bodily processes that lend credence to the idea that power is everywhere and not just in certain places[159]. For example, particular data in social history such as the level of education versus the presence or absence of a disease renders the knowledge computable and calculable for an array of political purposes. Therefore, as a structural interest; medical records create a platform as a form of social control in disciplinary institutions such as hospitals for reporting and

[157] Nikolas Rose and Peter Miller, 'Political Power Beyond the State: Problematics of Government' (1992) 43 The British Journal of Sociology 173, 200.
[158] Ibid 184.
[159] Ibid 186.

learning, providing calculations for hospital managers which then flow to higher levels such as the Ministry to formulate health policies for the interest of a nation.[160]

Medical records can be deemed to be an 'inscription device'[161]; a historical source to make comparable and combinable knowledge susceptible to evaluation, calculation, and intervention to pursue political rationalities.[162] They can be described as 'artefacts of biomedical knowledge'. [163] This includes medical professionals, health managers, policymakers and the public which further elevates the social significance of medical records and their use as a technology of discipline and social control. Medical records as technologies of government are arguably different from political rationalities as the former described 'methods' as opposed to 'reasonings' of government action. Technologies of government is another dimension of governmentality that includes different domains (legal, political, ethics), methods (statistics, research) and devices (medical records). This stands in stark contrast to the views of others that see medical records as a medical innovation capable of empowering individuals.

I have demonstrated that medical records have a social significance as legal artefacts and as a medical and ethical tool, while concurrently acting as a political technology. The diversities of these roles highlight interesting functions and issues around governmentality, which will be discussed later. They can also be seen as communicational constructs of social systems for medicine, as evidence for the legal system or as a statement of truth for the system of science in medicine. They can be a legal and ethical medium of social communication. This fundamental background about what medical records illustrate, their significance and why it is important to engage in questions on widening access is because they remain an integral part of

[160] Paul Joyce, ' Risk, Trust and Governmentality: Setting Priorities in the New NHS', University of Salford (1999).

[161] Rose and Miller, 'Political Power Beyond the State: Problematics of Government', 185.

[162] Ibid 183.

[163] Alice Street, 'Artefacts of Not-Knowing: The Medical Record, the Diagnosis and the Production of Uncertainty in Papua New Guinean Biomedicine' (2011) 41 Social Studies of Science 815, 822.

social systems of communication. Healthcare provision in many countries is continuously expanding, becoming more complex and costly, creating an environment necessitating expert authorities to manage issues involving 'differences', such as disputes between clinicians and patients. At present, the care of a single patient almost inevitably seems to involve many different individuals and groups, with the information generated by the patient's health status and the clinician's observation must be communicated effectively to bring meaning to the social system. Luhmann describes the interaction between these distinctions as social systems of communication.[164] An organisation such as a healthcare institution is a type of social system in which individual members or groups, together or apart make decisions through communication, rendering it meaningful and with purpose. For example, meaningful information is communicated reflexively through language.

Luhmann's theory can be applied to medical records. As a medical entry is created by an individual about another individual's body, his theory uses the domain system of communication (the medical entry) as part of the social system (providing healthcare). However, without eliminating an individual's significance in society (be it doctor or patient involved in the case), medical records is constructed according to the primitive and potential roles to mean something for a particular system of communication.[165] These constructs include a range of functions such as legal protection or sociological research as previous communications have allowed these meanings to inform its significance for others. Medical records, despite their distinct identity, allow other unique identities to emerge based on their differentiated meanings in particular circumstances; for example, evidence in a trial or as a technological tool for patient empowerment with wider patient access.

---

[164] Loet Leydesdorff, 'Luhmann Describe the Interaction between These Three Distinctions as 'Social Systems of Communication'' (2000) 17 Systems Research and Behavioural Science 273.

[165] John J Rodger, 'Luhmann's Theory of Psychic Systems and Communication in Social Work Practice' (2021) 22 Journal of Social Work .

The novelty of medical records acting as an accountability tool has seldom been explored. Horton defined accountability as the condition of being answerable for past actions.[166] The function of medical records is subject to institutional and social change. Within the medical records is a construction of a unique version of time concerning a patient's health status at various moments by relevant functional events within a healthcare provision. Horton explores Luhmann's concept of time[167] to inform the analysis of how accountability is constructed and communicated within a particular healthcare experience. Medical records, therefore, are probably the only tool and witness of communication that can account for the 'passage of time based on the available information within it'.[168] Therefore, ethically, the account of a patient's journey renders medical records the only journal that should be verified as 'truth' by the patient who experienced this journey.

Medical records' current status as source material in historical research is partly due to the rise of popular interest in social history and, by extension, the study and interpretation of data relating to ordinary people. A new generation of social historians (including scholars with backgrounds in anthropology, ethnology, evolutionary psychology, sociology, population studies and genetics) has demonstrated the importance of birth records and parish registers as primary sources of information.[169] Patient records have been linked to several topics in studies of current medical history. The modern tradition of medical record keeping has been valuable in allowing historians and physicians in several medical and medicine-related fields of

166 David P Horton, 'Accountability and Time', *Mental Health Homocide and Society: Understanding Health Care Governance* (Hart Publishing 2019) 129.
167 Ibid.
168 Ibid 129.
169 Guenter B Risse and John Harley Warner, 'Reconstructing Clinical Activities: Patient Records in Medical History' (1992) 5 Social History of Medicine 183,185.

speciality. Medical records can also help society to understand how hospital organisations and medical practices interact.[170]

Within the distinctions that can be observed, medical records can be distinguished from other medical documentation and become a system of communication and a historical account of their environment by referring to their own operations and previous communication. As a social system, medical records preserve their systemic integrity but presuppose specific states or changes in the environment.[171] They record details about the patient's history, clinical findings, test results and progress as well as support the doctor in finding the right treatment and are important in every medico-legal case in court.[172] It is this concept that explains why medical records can deliver both primary functions and social functions due to the coordination, adaptation and adjustment between these different functions using previous communication in their respective environments. Thus, they serve as constructs for these systems. They have specific meaning and intention for these systems which eventually builds up to be of social significance to society (systems theory) and to theories of social control (governmentality).

## 1.9 Conclusion

In this chapter, I have described the two most common formats of medical records and their utility based on their physical and sociological characteristics. Various healthcare institutions and systems have constantly expanded the medical records' accessibility and multiple configurations to continually evolve. The introduction of EMR as the 'appropriate interface' allows even more access and is more easily configurable or customised.

---

[170] Nora Aslinda Mohd Amin and Saiful Farik Mat Yatin, 'Role of Medical Records Management Practice in Improving Decision Making in University Hospital' (2020) 10 International Journal of Academic Research in Business and Social Sciences 1160.

[171] Horton, 'Accountability and Time'.

[172] Bali and others, 'Management of Medical Records: Facts and Figures for Surgeons', 199.

Their versatility also allows them to be the basis for multiple heterogeneous roles serving various purposes in society. Apart from their role in health, it is important to explore the social significance of medical records as it helps to define and engage the question of why we need to widen access, especially to patients. Crucial to the evolution of medical records' diversity of functions and integrations to higher social purposes beyond their initial intended role is one of the most important factors: access. It is the 'generative' role that allows medical records to become versatile beyond their conventional function. It evolves into a 'method' that allows governmentality and social system to thrive under its performance. In this thesis, we will ethically justify how widening access to patients is a natural and essential progression of this evolution as medical records continue to propagate and benefit different users.

# Chapter 2. Malaysian legal and regulatory position on patient access to medical records

## 2.1 Introduction

This chapter will discuss and analyse the Malaysian legal and regulatory position on patient access to medical records. First, I will outline Malaysia's legal and health provisions that relate to patient access to medical records including the procedure and introduce the regulatory bodies that are involved in the regulation of access and the management of medical records. The Malaysian legislation comprises of three Acts – the Medical Act 1971, the Personal Data Protection Act 2010 and the Private Health Facilities and Services Act 2006 – that indirectly cover patient access to medical records. However, there are concerns as to the capacity of these legislative instruments to protect patients and to give right of access to medical records, and whether the legislation contains useful mechanisms in determining this right. The regulatory landscape in healthcare will also be highlighted, emphasising the rules and regulations on patient access to medical records.

This chapter also examines the ambiguity in the ownership of medical data in Malaysia and the procedures for granting access to patients. It is important to unpack this issue as restrictions of patient access to medical records are mainly due to ownership status that was derived from the MMC Guidelines on Medical Records and Reports.

Malaysia is a multi-ethnic and middle-income country[173] with a multicultural and diverse racial population where the majority are Malays, followed by Chinese, Indians and indigenous people. The population is 33 million of which Malays and indigenous people comprise 62.5%

[173] Zainal Aznam Yusuf and Deepal Bhattasali, *Economic Growth and Development in Malaysia: Policy Making and Leadership* (2008).

and Chinese, Indians and other races comprise 20.6%, 6.2% and 0.9% respectively.[174] Islam (61.3%) is the official religion in Malaysia, but with the freedom to practise other religions including Buddhism (19.8%), Christianity (9.2%) and Hinduism (6.3%).[175] It is a federation of 13 states and three federal territories of which nine states are ruled by hereditary sultans, with four by governors and the federal territories being under the purview of the federal or central government. Malaysia upholds parliamentary democracy and is led by a constitutional monarch, the Yang di-Pertuan Agong, who is elected for a five-year term from the nine hereditary rulers).[176] Following the federation's general structure, each state has an assembly and a government led by a chief minister. The Federal and State Constitutions define the division of legislative powers between the federal and state governments. This ensures the state government administration is autonomous, but with certain exceptions as defined in the Federal Constitution which gives the Federal government the rights to certain policies such as health, even at the state level.[177]

## 2.2 The Malaysian legal system

The Malaysian legal system is predominantly based on the English model of common law which led to my decision to use the latter as the main comparator (see Chapter 3).[178] Despite

[174] Mohsen Kadivar, 'An Introduction to the Public and Private Debate in Islam' (Social Studies Conference).

[175] Index Murni, 'Malaysia Demographics Profile' (2021) <https://www.indexmundi.com/malaysia/demographics_profile.html#:~:text=33%2C519%2C406%20(July%202021%20est.)&text=Bumiputera%2062.5%25%20(Malays%20and%20indigenous,9.8%25%20(2019%20est.)&text=The%20World%20Factbook%2C%20the%20indispensable%20source%20for%20basic%20information.>, accessed 15 September 2022.

[176] Shaikh Mohamed Noordin and Shanthi Supramaniam, *Update: An Overview of Malaysian Legal System and Research* (Houser Global Law School Program, New York University School of Law 2016).

[177] Martin Rudner, 'The Structure of Government in the Colonial Federation of Malaya' (1976) 13 South East Asian Studies .

[178] Tun Abdul Hamid Mohamad and Adnan Trakic, 'The Reception of English Law in Malaysia and Development of the Malaysian Common Law' (2015) 44 Common Law World Review 123.

both systems sharing a common legal heritage and culture, other comparisons yield advantages and benefits which will also be explored.

The judiciary is made up of the Federal Court (the highest court), the Court of Appeal and two High Courts (one for Peninsular Malaysia and the other for Borneo and Sarawak) and several subordinate courts such as the Sessions Court. The Yang di-Pertuan Agong appoints judges based on the recommendation of the administration.[179] In 1985, the possibility of a final appeal to the UK Privy Council was eliminated, making the Federal Court of Malaysia the court of last resort.[180]

Fundamental rights are rooted in the nation's legal and political framework with the Federal Constitution of Malaysia as the Federation's supreme law and any law that is unconstitutional under the Constitution can be challenged in court. The Malaysian Federal Constitution upholds uniformity, liberty and social equity and plays a key role in establishing the separation of powers between the legislature, executive and judiciary, including overseeing the distribution of powers between federal and state authorities. The Malaysian Constitution's supremacy provision has been considered a natural outgrowth of the courts' authority of judicial review over the constitutionality of legislation.[181] The Federal Court of Malaysia, as the country's highest court, hears appeals from the Court of Appeal and has exclusive jurisdiction over federalism issues and disputes arising between the Federation and individual states.[182]

---

[179] Noordin and Supramaniam, *Update: An Overview of Malaysian Legal System and Research*.

[180] Yvonne Tew, 'On the Uneven Journey to Constitutional Redemption: The Malaysian Judiciary and Constitutional Politics' (2016) 25 Washington Internaltional Law Journal Association 673, 677.

[181] Noor Ashikin Hamid and others, 'Erosion of the Concept of Constitutional Supremacy in Malaysia' (2019) 4 International Journal of Law, Government and Communication 27.

[182] *World Bank Report, Court Backlog and Delay Reduction: A Poverty Reduction and Economic Management Sector Unit East Asia and Pacific Reg, (2011).*

## 2.3 The Landscape of Medical Negligence in Malaysia

Medical negligence claims are on the rise in many countries, including Malaysia.[183] Although comprehensive annual statistics on medical negligence claims are not available for Malaysia, an increase in the number of claims of medical malpractice has led to a high amount of costs in rectifying the complaints.[184] While Malaysia is currently not going through a 'malpractice crisis' on the scale of other nations like the United States and the United Kingdom, the amount of money the government must set aside for healthcare will increase in line with the growing number of medical claims.[185] The medico-legal unit in the Ministry of Health is responsible for managing investigations of medico-legal complaints and ex-gratia resolutions (compensation given without any liability obligation). The unit also coordinates with the Attorney General's Chambers in matters of medical practice litigations. In the years 2012-2021, the statistics from the Ministry of Health reported 675 cases that were awarded ex-gratia payments to a total amount of RM 50 million (~10 million GBP), while in 881 cases the compensation was awarded in medical litigation cases in court, with the total amount of RM190 million (~40 million GBP).[186] As there has been no report prior to this, an objective inference to suggest that medical claims are increasing would be difficult. However, the report in its form and rights to be published by the Ministry of Health suggests that this is likely so.

Medical complaints are received covering a variety of areas, including services and facilities, but poor service or poor communication skills between doctors and nurses were among the complaints the Malaysian Ministry of Health received from the general public. As a result of negligence, the ministry was required to pay roughly RM 20 million in compensation each

[183] SN Hambali and S Khodapanahander, 'A Review of Medical Malpractice Issues in Malaysia under Tort Litigation System' (2014) 6 Global Journal of Health Science 76, 76.
[184] Ibid 77.
[185] Puteri Nemi Jahn Kassim, *Medical Negligence Litigation in Malaysia: Current Trend and Proposals for Reform*)
[186] Ministry of Health, *E-Bulletin Medico Legal Section* (2022).

year.[187] The Health Minister attributed these incidents to ineffective communication, lack of teamwork, heavy workload, staff fatigue and failure to follow procedure.[188] Both the government and the Bar Council offer legal assistance to help offset the high expense of litigation, but sadly, the programme has very few resources, and many complainants are excluded because they are not eligible.[189]

In addition to the expenses, the lengthy period for pursuing claims is significant. Delays can occur in medical negligence cases before the plaintiff seeks legal counsel. At the same time, experts need to investigate the case and produce their report, exchanging documentary evidence and waiting for the trial date. There is little doubt that these delays add to the time needed to resolve the case. In the case of *Dr Chin Yoon Hiap v Ng Eu Khoon & Ors and other appeals*,[190] it took nearly 16 years to resolve a lawsuit that was started in 1981 and concluded in 1997. Furthermore, in *Foo Fio Na v Hospital Assunta & Anor*,[191] the cause of action took place in 1982, but the High Court's ruling and the Court of Appeal's ruling were made in 1999 and 2001 respectively; the application for leave to appeal to the Federal Court against the Court of Appeal's ruling was finally issued in 2006 in the Federal Court. Thus, it took 24 years for the issue to be resolved in its entirety from the High Court to the Federal Court. From the date of the injury until the resolution of the case, it can be observed that the full litigation process for a medical negligence lawsuit requires an average of around 15 years.

---

187 Ili Shazwani, 'Health Ministry Gets 7,000 Complaints, Spends Rm20mil on Compensation Annually' *New Straits Times* (<https://www.nst.com.my/news/nation/2017/11/299206/health-ministry-gets-7000-complaints-spends-rm20mil-compensation-annually>.

188 Alifah Zainuddin, 'Cases on Medical Negligence on the Rise, Health Ministry's Data Shows' *The Malaysian Reserve* (<https://themalaysianreserve.com/2019/09/18/cases-on-medical-negligence-on-the-rise-health-ministrys-data-shows/>.

189 Hambali and Khodapanahander, 'A Review of Medical Malpractice Issues in Malaysia under Tort Litigation System', 78.

190 *Dr Chin Yoon Hiap v Ng Eu Khoon & Ors* [1997] 1 All ER 871.

191 *Foo Fio Na v Hospital Assunta & Anor* [2007] 1MLJ 593.

A legal action in process against a doctor will affect the doctor's credibility. Therefore, the increase in medical negligence claims will prompt physicians to practise 'defensive medicine' in which they over-investigate or over-treat patients irrationally in order to prevent being held liable for any potential negligence (see Section 2.3). No data on defensive medicine in Malaysia is available,[192] but prevention of medical litigation through an alternative system can be in the form of a 'no fault compensation' scheme similar to that implemented in New Zealand. As part of a collective responsibility, the social insurance plan would include compensation plans for any personal injuries resulting from medical errors or malpractice, whereby fault will become non-relevant.[193] At present, the UK is also considering this as part of an alternative, as it still heavily relies on compensation through litigation. By implementing this system, the procedure would proceed quickly and there would be less need for legal fees, while patients who suffered harm or damage would be compensated. It might address the NHS blame culture so that doctors would not be discouraged from reporting accidents and could limit the practice of defensive medicine.[194] Under this system, the specific doctor would not be held accountable for the personal injury. No-fault compensation would only be used for the patient's well-being and not for the cost of the legal proceedings. Although the compensation might be less than what the patient might get if they won in court, it would relieve both parties from the very emotional experience of going to court.[195] Malaysia should consider adopting as well as studying the cost-

[192] Rozlinda Mohamed Fadzil, Asma Hakimah Abd Halim and Ain Alya Ariffin, 'Defensive Medicine as a Result of Medical Negligence: A Brief Overview' (2018) 2 UNTAG Law Review 70, 72.

[193] Puteri Nemie Jahn Kassim, 'Medical Negligence Disputes in Malaysia:Resolving through Hazards of Litigation or through Community Responsibilities?' (2013) 7 International Journal of Humanities and Social Sciences 1757.

[194] Luke Haynes, 'Gps Demand End to Defensive Medicine Via 'No Fault' Compensation Scheme' (*GP Online - Haymarket Media Group Ltd,* 2022) <https://www.gponline.com/gps-demand-end-defensive-medicine-via-no-fault-compensation-scheme/article/1755705>, accessed 7 July 2022.

[195] Jahn Kassim, 'Medical Negligence Disputes in Malaysia:Resolving through Hazards of Litigation or through Community Responsibilities?', 1761.

effectiveness of the scheme, as the no-fault compensation has a high financial commitment initially to make it work.

As mentioned earlier, together with the probability of an upward trend in medical negligence cases in Malaysia, this thesis suggests that doctors and hospital providers might refuse patient access to records in fear of litigation. A cross-sectional study was performed in a hospital in northern Malaysia, which included doctors as the respondents (449 doctors). The study shows that only 10.1% of doctors would disclose medical errors, as the respondents (40%) were of the opinion that they would less likely be sued if they were not to disclose.[196] In most medical litigation cases, the burden to prove the balance of probability that a breach of doctors' standard of duty did occur lies on the shoulders of the plaintiff and not the defendant. For that purported reason, obtaining medical records is important to identify at an early instance if negligence occurred from the defendant side. As depicted in Chapter One, medical records are an accountable tool which illustrates a very important social significance; information on the healthcare trajectory of a patient acts as a power of knowledge (see Section 1.8 ). Therefore, patient access to medical records may in turn provide a cause of action to sue for the patients (plaintiff) and consequently may tarnish the doctor's reputation as well as future prospects in his or her career.

However, it can be argued that providing access to information may also be part of resolution to the pursuance of medical claims, which is known to be a lengthy and costly process from the doctor's and patient's perspective. Thus, where doctors meet the patient's need for information by disclosing the medical records voluntarily, this may provide more instantaneous

[196] Arvinder-Singh and Abdul Rashid, 'The Intention to Disclose Medical Errors among Doctors in a Referral Hospital in North Malaysia', 4.

and realistic information for patients and they may not need to seek civil action once their concerns have been addressed.

## 2.4 The process to access medical records

One of the key reasons medical records are useful is in legal proceedings for medical negligence.[197] To gain a proper perspective, it is important to understand the legal development and the process of securing access to these records. As it is used during the discovery process to establish cause, parties such as doctors or hospital providers who have the authority to keep medical records might be reluctant to release them as they might prove incriminating.[198]

The MMC Guidelines claimed that the patient should: (1) have access to records containing information about their medical condition for legitimate purposes and in good faith; (2) know what personal information is recorded; (3) expect the records to be accurate; and (4) know who has access to their personal information.[199] The MMC Guidelines also suggest that increased access to medical records has provided patients with a better understanding of their illness and has a positive impact on the patient-doctor relationship. Patients may be allowed to tell the practitioner of any factual mistakes in their personal information.

However, in reality, medical records in Malaysia can only be obtained through a court order.[200] While attorneys occasionally request medical records on behalf of a patient, not all requests are for litigation against a doctor or hospital. There are two methods by which medical records

---

[197] Mohd Mokhtar, 'The Law and Challenges to Access Medical Records for Medical Negligence Claims in Malaysia', 44.
[198] Ibid 49.
[199] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.7.
[200] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors; Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors.*

can be obtained under the Rules of Court 2012 in Malaysia. The first is by way of discovery, and the second by subpoena.

'Discovery' was defined in *Mulley v Manifold*: In this Australian case, the plaintiffs demanded injunctions and a declaration that a committee decision was void.

> Discovery is a procedure directed towards obtaining a proper examination and determination of these issues – not towards assisting a party upon a fishing expedition. Only a document which relates in some way to a matter in issue is discoverable, but it is sufficient if it would, or would lead to train of inquiry which would, either advance a party's own case or damage that of his adversary.[201]

Discovery is thus a method of gathering evidence in civil litigation.[202] It allows parties to exchange relevant documents and is an important part of the legal procedure as it enables the plaintiff's lawyer to assess the prospects of success of a claim as early as possible and advise patients who have no direct or physical access to their medical records. Medical records are considered as part of the discovery of documents but are held by another party.[203] The plaintiff must persuade the court that the papers are relevant to the case and are in the opposing party's possession or control.[204] The court must oversee the discovery process, which primarily aims to determine the substance of the case. The High Court has the authority to determine the order of discovery.[205] There are several stages including the pre-trial procedure, the course of pleading in an action in the High Court that occurs after service of the reply, the defence to the claim and the defence made after the issuance of a writ.[206] The patient's medical records are vital in determining the claimant's prospects in cases of medical negligence before the start of

---

201 *Mulley v Manifold* [1959] 103 CLR 341[7].

202 Duryana Mohamed, 'Discovery and Inspection of Documents under the Malaysian and English Civil Procedure: A Study on Cases against the Internet Service Providers' (2012) 6 Australian Journal of Basic and Applied Sciences 185, 185.

203 Habibah Omar, *Law of Evidence in Malaysia* (Second Edition edn, Sweet & Maxwell 2018).

204 Mohamed, 'Discovery and Inspection of Documents under the Malaysian and English Civil Procedure: A Study on Cases against the Internet Service Providers', 187.

205 Courts of Judicature Act 1964, s 25(2).

206 Rules of Court 2012.

an action. It is in the interest of all parties to determine whether litigation should be discontinued if there is no chance of success and prior knowledge using medical records is part of the discussion. This would eliminate any waste of resources and time for the parties. However, at no point during this process does a patient has automatic, physical or direct access to medical records and their contents.

The only way for a patient to obtain their medical records is through pre-trial discovery which commences after the close of pleadings. This procedure was previously governed by the Rules of the High Court 1980[207] but is now covered by the 2012 rules under which there is no mutual discovery of documents without an order from the court. Unfortunately, the rules do not extend to the discovery of documents in the pre-action stage and remove the mutual or automatic discovery by consent. Order 34[208] compels parties to produce all information and documents as required by the court. However, any information which is privileged from disclosure shall not be required to be given otherwise without the consent of the party.

According to the 2012 rules, there are two types of document discovery. A party must compile and serve on the opposing party a list of all documents related to the case at hand that are currently or have previously been in their possession, custody, or control to request general discovery.[209] For specific discovery, a court order must be sought in relation to a particular document and the order does not take effect unless a general discovery order has been obtained with the opinion of the court that the order is necessary or desirable.[210] This indicates that the discovery of documents would only be permitted following a party's application and a discovery order by the court. Since the procedure aims to give parties all pertinent information and documentary proof and to do away with the element of surprise, the other party is expected

[207] Ibid order 24.
[208] Ibid order 34, r 8.
[209] Ibid.
[210] Ibid. General discovery order 24 r 3. Specific discovery, order 24 r 7.

to abide by the court's order and produce the documents.[211] However, if the discovered document is a medical record, it cannot be provided without the authorisation of the Director of the hospital who acts as the guardian of the records.[212] The steps to grant access to medical records after receiving a written request on behalf of patients can occur before or during the process of discovery.

A subpoena is often used by parties to seek evidence from a non-witness party and it entails the production of medical records by an attorney.[213] The problem of a subpoena issued by a judge will come up while the legal case is still being heard. There are three types of subpoena: (1) *subpoena ad testificandum*, or subpoena to testify; (2) *subpoena duces tecum* or subpoena to produce the document; and (3) subpoena to testify and produce documents. Considering that a writ is used to start legal proceedings and allow for the process of discovery, the rules[214]enable anyone served with a subpoena to produce papers to comply if they arrange for the production of the document without attending personally.

Therefore, when testifying, doctors who have been served with a *duces tecum* subpoena are expected to bring certain documents, typically the original medical records. A subpoena may also direct the defendant to deliver the documents as quickly as feasible to the court's registrar in certain civil cases before the High Court.[215] If the documents are used in evidence, members of the hospital must first receive the order so that the photocopy of the records is required and the original document is kept and returned after the copy is made to prevent loss of data or damage. Hospitals must not disobey a subpoena order which commands the medical record to

---

211 Mohamed, 'Discovery and Inspection of Documents under the Malaysian and English Civil Procedure: A Study on Cases against the Internet Service Providers', 187.

212 Ministry of Health, *Guidelines for the Management of Patients' Medical Records for Hospitals and Medical Institutions* (2010), cl 9.

213 David J Lender, 'Subpoenas:Using Subpoenas to Obtain Evidence' 2013), accessed 13 August 2021.

214 Rules of Court 2012, order 38 r 16.

215 Ibid order 38 r 20.

be released but it is the hospital Director who consents to the release. When hospitals disobey it would be considered contempt of court.[216] If there are grounds to not publish the records and refuse to provide proof, 'reasonable reasons' must be clarified before the Court during the hearing of the subpoena.[217]

## 2.5 The recourse to legal channels and its challenges

One argument that healthcare providers may use against patient access to medical records is that it will lead to an increase in litigation.[218] The need to obtain these records is important for the patient to find out whether they have a good cause of action before the commencement of proceedings. Difficulty in obtaining medical records may arise and stems from the fact that the documents are in the possession of the doctors or health providers who are potential defendants in the proceedings. It is customary to initiate an action of medical negligence from the information received to establish any misconduct of medical treatment from the medical records. All these particulars can only be secured if the patient has wider and automatic access to their own medical records which at present, they do not. There appear to be two dynamics of conflict. The first is from the court in the form of legal sanctions, should the hospital refuse as hospitals must not disobey a subpoena order which orders the medical records to be released (see Section 2.4).[219] The second is the hospital providers which own the medical records. The law that was founded on the tenet of 'discovery' established by Order 24 requires the plaintiff to request a court order before being granted access to medical records. To prove their cause

---

[216] *Perbadanan Nasional Berhad v Syed Omar Syed Mohamed* [2011] I LNS 96. The court ordered the case to be struck out for failure to comply with court order.

[217] Rosseriyani Don, 'How to Handle the Medico Legal Cases' 2017) <http://www.myhealth.gov.my/en/handle-medico-legal-cases/>, accessed 13 Sept 2021.

[218] Hambali and Khodapanahander, 'A Review of Medical Malpractice Issues in Malaysia under Tort Litigation System', 79.

[219] *Perbadanan Nasional Berhad v Syed Omar Syed Mohamed.*

of action during the preliminary proceeding in medical negligence lawsuits, patients may ask to access their medical records but hospitals may be reluctant to accept such requests as it may be potentially damaging to them. As it stands, only the courts can compel access.[220] This is an instance of defensive medicine and perhaps a tendency amongst hospitals to act defensively as refusing patient access to their medical records may be seen as a potential cause of litigation. However, patients may view the denial of access as evidence of a cover-up.[221]

Arguably, the fear of medical professionals being sued for malpractice has led to defensive medicine (see Section 2.3). Fear of confrontation or retaliation has led them to take precautions, which include practising defensive medicine to reduce such risk.[222] They may request investigations and perform procedures that may not be necessary to 'cover all angles', causing increased cost, delays in management and unnecessary anxiety. This can be applied to medical records as doctors may document clinical entries to avoid litigation and therefore spend more time on defensive practices that impact clinical time with patients.[223] The notion that a doctor should be able to withhold records to reduce the possibility of litigation is ethically and practically difficult to justify given that the records would often provide the only means of knowing whether there is any basis for an action and that they are in any case discoverable once litigation begins. To deny access, therefore, results in a situation whereby patients are forced to start litigation before they can discover whether there is any valid basis for commencing litigation.

The other prominent effects are financial and mental burden for patients. A lawsuit is not a simple process and carries many stages and processes. It will be foreseen as a difficult process

---

[220] Refer to case *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors.*

[221] Heidi Tranberg and Jem Rashbass, *Medical Records Use and Abuse* (Radcliffe Medical Press 2004), 81.

[222] Mohamed Fadzil, Abd Halim and Ariffin, 'Defensive Medicine as a Result of Medical Negligence: A Brief Overview', 72.

[223] Parthapratim Gupta, 'Avoiding Litigation in Clinical Practice' (2019) 24 Journal Indian Association of Pediatric Surgeons 158.

by patients because it will involve many different stakeholders and might drag on for up to 25 years.[224] Costly expert witnesses are needed. There will be a lot of paperwork and protracted legal actions are by nature onerous. It will be expensive and need a great deal of personal tenacity.[225] As the plaintiff lacks the financial means to obtain the justice they are entitled to, this leads to a chain of events in which they could suffer emotional or physical harm. Permanent harm, job loss and lost wages are just some of the potential negative effects. For the plaintiff, their medical expenses may be incurred continually for the remainder of their lives.

## 2.6 Legal positions and their utility to determine patient access to medical records

### 2.6.1 Personal Data Protection Act 2010

The PDPA is the statutory regulation most relevant to the topic of access to medical records and came into force in November 2013. With it, Malaysia became the first country in Southeast Asia to enact a data protection law.[226] It was based on Hong Kong's Personal Data (Privacy) Ordinance 1995 and the UK's Data Protection Act (DPA) 1998[227] with modifications to adapt it for Malaysia.[228]

The PDPA applies to any person who processes or has control over or authorises the processing of any personal data in respect of commercial transactions.[229] It governs how personal data is collected, used, transferred and deleted. Any person who processes personal data ('data user')

---

224 Mohamed Fadzil, Abd Halim and Ariffin, 'Defensive Medicine as a Result of Medical Negligence: A Brief Overview', 81.

225 *Foo Fio Na v Hospital Assunta & Anor* Foo Fio Na v Hospital Assunta & Anor 1MLJ 593 (2007).

226 Oan Suet Yen, 'The Malaysian Personal Data Protectcon Act 2010: A Brief Overview' 2010) <http://www.taypartners.com.my/en/images/OurResources/Articles-LegalTaps/legaltaps-201008.pdf>, accessed 23 May 2021.

227 Edwin Lee, 'Limitations of the Personal Data Protection 4 Act 2010 and Personal Data Protection in Selected Sectors' in Noriswadi Ismail, Yong Cieh and Edwin Lee (eds), *Beyond Data Protection : Strategic Case Studies and Practical Guidance* (2013th edn, Springer 2013), 74.

228 Hong Kong Personal Data (Privacy) Ordinance 1995; Data Protection Act 1998.

229 Personal Data Protection Act 2010, s 2(1).

of an individual ('data subject') is required to comply with the seven personal data protection principles ('PDP principles') under the PDPA.[230] Under Section 4, a data user is defined as a 'person who either alone or jointly, or in common with other persons processes any personal data or has control over or authorises, the processing of any personal data but does not include a data processor'.

It is important to establish whether or not someone is a data user because Section 5(1) provides that it is the data user that must comply with the PDP principles and other related provisions. Section 14 provides that if the data user falls within a class of data users specified in an order made by the Minister, such data user is required to register with the PDP Commissioner following the registration provisions laid down in Division 2 of the PDPA. However, all other data users who are not required to register with the Commissioner must still comply with all the provisions of the PDPA, including the principles, except the registration provisions stated in Division 2. In other words, as long as the person is involved in processing personal data, they are subject to the PDPA.

Apart from the data user, there is another category of person who processes personal data. Under section 4 of the PDPA, such a person is known as a 'data processor', defined as 'any person, other than an employee of the data user, who processes the personal data solely on behalf of the data user and does not process the personal data for any of his own purposes'. As Section 5(1) provides that only a data user has to comply with the PDP principles and Section 4 expressly excludes the data processor from the definition of the data user, a data processor therefore, does not have to comply with the PDP principles. However, if the processor processes personal data for their own purposes, then they become a data user and must comply with all of the PDP principles. This section ensures that the processing of personal data is

[230] Ibid. Seven Principles include 1) General Principle 2) Notice and Choice Principle 3) Disclosure Principle 4) Security Principle 5) Retention Principle 6) Data Integrity Principle 7) Access Principle.

carried out by a data processor on behalf of the data user, but the onus is on the data user to take steps to ensure that the data processor complies with the principles. This requires the data processor to provide sufficient guarantees with respect to the technical and organisational security measures and take reasonable steps to ensure compliance with those measures.[231]

The PDPA also states that 'manual data' includes data recorded or intended to be recorded as part of a 'relevant filing system', defined in Section 4 as:

> Any set of information relating to individuals to the extent that, although the information is not processed by means of equipment operating automatically in response to instructions given for that purpose, the set of information is structured, either by reference to individuals or by reference to criteria relating to individuals, in such a way that specific information relating to a particular individual is readily accessible.

Electronic or computerised data is not defined in the PDPA but it can be deduced from Section 4 which applies to personal data that includes data being processed or recorded with the intention that they should wholly or partly be processed using equipment operating automatically. For example, all data stored on a computer is considered electronic data by the Act, which is relevant to EMR and EHR.

According to Section 4 of the PDPA, personal data is 'any information in respect of commercial transactions'. Secondly, the existing PDPA legislation in Section 2(1) states that PDPA applies to any person who processes, has control over or authorises the processing of any personal data in respect of 'commercial transactions'. The definition of 'commercial transactions' is clearly defined in Section 4 as:

> Any transaction of a commercial nature, whether contractual or not, which includes any matters relating to the supply or exchange of goods or services, agency, investments, financing, banking and insurance, but does not include a credit reporting business carried out by credit reporting agency under the Credit Reporting Agencies Act 2010.

[231] Ibid.

Thus, the meaning of 'commercial transactions' is crucial to understanding the nature of the personal data protected under the Act.

### 2.6.2 Medical Act 1971

Other statutory regulations exist that are relevant to patient access to medical records. These include the Medical Act 1971:

> an Act to consolidate and amend the law relating to the registration and practice of medical practitioners and for national purposes to provide for certain provisions with regard to a period of service in the public sector after full registration as a medical practitioner; and to make provision for purposes connected with the aforesaid matter.[232]

Pursuant to Section 29(1), the MMC has disciplinary jurisdiction over registered medical practitioners and is thus a statutory body. The role of MMC will be explained further in the later part of this chapter.

The Act does not explicitly discuss the consequence of a breach of MMC Guidelines. For example, if a patient requests access to their medical records for 'legitimate purpose and good faith, such as to know that the information recorded is accurate', as stated in Clause 1.7 of the Guidelines,[233] and the doctor does not allow this access, it is difficult to ascertain if there is a breach in the rules. Without a clear consequence of a breach, there is a reluctance to healthcare providers to allow access and a perception that access can only be obtained through a court order.

The Act permits the MMC to exercise disciplinary jurisdiction in five circumstances and they do not include violations of the Guidelines.[234] In Malaysia, the MoH and its Board of Inquiry handle general complaints against medical professionals working in public services, including

---

[232] Medical Act 1971). See page  in the explanatory.
[233] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*.
[234] Medical Act 1971, s 30(1).

those involving ethical and disciplinary violations in line with the Good Medical Practice 2019 and Code of Professional Conduct 2019.[235]

### 2.6.3 Private Healthcare Facilities and Services Act 1998

The private health sector, including medical clinics, dental clinics, hospitals and other services, is regulated under the PHFSA 1998 (Act 586) which came into force in 2006. Private healthcare in Malaysia began to expand in the 1980s with a concentration on hospitals and specialised care.[236] This contributed to social concerns about private healthcare, forcing the government to enact the PHFSA to regulate private hospitals. The Act requires a private proprietor to apply for a licence from the MoH and to meet basic standards. MoH authorised officers have powers to inspect and investigate when there are serious concerns or complaints. [237] As a result, the Malaysian government is deeply involved in the private healthcare system which is rapidly evolving, notably to improve the balance between the private and public sectors in healthcare provision and funding as many private hospitals face challenges in compliance with the new regulations.

The MoH has a limit on its authority and does not apply itself to private clinics and hospitals, where the MMC's main role is to regulate the practice of medicine and register medical professionals. Neither has the jurisdiction to impose restrictions on patients' right to access medical records from private medical practitioners, as neither the Medical Act 1971 nor the MMC Guidelines provide for or authorise such actions. Thus, PHFSA was passed to govern the management of private clinics.

---

[235] Medical Regulations 1974.

[236] Heng Leng Chee, 'Ownership, Control, and Contention: Challenges for the Future of Healthcare in Malaysia' (2008) 66 Social Science & Medicine 2145, 2146.

[237] Private Healthcare Facilities and Services Act 1998.

For medical records, the PHFSA gives due importance to security concerns and restricts patient access to medical records. They must be stored in a safe and secure room, accessible and retrievable when required and returned in complete form. Regulation 30(2) provides that:

> No patient's medical record shall be taken out from the private healthcare facility or service except under a court order and when taken out from the private healthcare facility or service under a court order, a copy of the records shall be retained by the private healthcare facility or service and the original records shall be returned to the private healthcare facility or service at the end of the proceedings for which the records were directed to be procured.

This Regulation is intended to ensure that the original records should be kept within the private healthcare facility and not be removed unless with a court order. If they are so removed, a copy must be retained by the institution and the original returned to the institution at the end of the proceedings. Despite no specific sanctions specified in the Regulation, it is stated that any person who contravenes the regulations has committed an offence. Therefore, for paper-based medical records, access is only possible if copies are made and filtered.

The Act provides for a system of licensing of the management of private hospitals, private nursing homes and private maternity homes and seeks to ensure quality and safety, particularly in relation to consultation and procedural fees. However, the Act does not include data protection policies or provisions about giving patients access to medical records.[238]

## 2.7 The relevance of PDPA and other legislation in accessing medical records

The main focus of this study is on the seventh principle of the PDPA which stipulates the principle of access to personal data. Section 12 provides that:

> A data subject shall be given access to his personal data held by a data user and be able to correct that personal data when the personal data is inaccurate,

[238] Wan Abdullah and Nik Rosnah, 'Medical Regulation in Malaysia: Towards and Effective Regulatory Regime'.

> incomplete, misleading, or not up-to-date, except when compliance with a request for such access or correction is refused under this Act.

The lack of concise provision and enforcement in the current PDPA and whether it applies to medical records is questionable. It fails to mention whether 'personal data' includes medical records and so is of limited use when it comes to access to those records. Even with the enactment of the PDPA where data protection can be adopted in sectors such as banking and finance, it does not appear to cover all aspects of data protection in healthcare. The PDPA provides certain exemptions from its application in healthcare, such as personal data in relation to mental health where it may result in serious harm to the subject or others.[239] Processing is defined widely under the PDPA to cover a wide range of activities including using, disseminating, collecting, recording and storing personal data. However, parties in the healthcare sector and their employees must resort to protecting the data subjects' personal data by invoking the common law duty of confidentiality.

While the PDPA contains a mechanism through which individuals can access data, it appears that it has limited use for accessing medical records. There are compelling reasons that the Act is weak when it comes to protecting patients' right to access these records. To ensure a consistent standard for granting rights to patients, Malaysia should change the Act so that its provisions apply to all data subjects and users without any restriction and does not place any constraints on the use of the Act.

The Act does not specify whether the concept of personal data includes medical records, but it may be inferred. However, of more significance, the PDPA could not be inferred to public hospitals as Section 3(1) states that 'this Act shall not apply to the Federal government and State Governments'. As all public and university hospitals are owned and operated by the government of Malaysia, it is the largest holder of personal data information in the form of

[239] Personal Data Protection Act 2010, s 45 (2)(b).

medical records but as the PDPA does not apply, its use is ineffectual as a platform or means to widen patient access.

As the main regulator of PDPA is the Ministry of Communications and Multimedia Commissions (MCMC), the role of the MoH has also become attenuated as the Act is more applicable for personal data in commercial transactions. Therefore, the cause, practice and effects of this Act were not naturally designed for the public sector, including the healthcare system. Although health data is not specifically defined in the PDPA, the data would fall within the scope of 'sensitive personal data' as it consists of the information on the 'physical or mental health or condition of a data subject'.[240]There are circumstances in which information might be withheld to prevent serious harm to the patient including therapeutic privilege which is a professional consideration that affects a decision to withhold information from the patient. Section 45 states:

> There shall be exempted from the provisions of this Act […] processed in relation to information of the physical or mental health of a data subject shall be exempted from the Access Principle and other related provisions of this Act of which the application of the provisions to the data subject would be likely to cause serious harm to the physical or mental health of the data subject or any other individual.

Thus, the PDPA considers the status of therapeutic privilege in English case law and concludes that, while reference is made to circumstances when information primarily in relation to risk disclosure may be withheld, further clarification is required on the status of therapeutic privilege. Therapeutic privilege, or better known as 'therapeutic exception' in the English law, exempted doctors from disclosing material risks associated with medical treatment if the law considered that the disclosure would be detrimental to a patient's health[241] (see Part Two on

[240] Ibid s 45(2)(b).

[241] Rachael Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis' (2017) 70 Current Legal Problems 149.

Ethical Analysis). This concept, however, in line with Section 45 of the PDPA, is not specifically defined in the Act.

According to the Minister of Health, the reason why the PDPA does not apply to the Federal and State governments is that they already have a legal mechanism in the Official Secret Act (OSA) 1972 to protect and safeguard personal data held by the government.[242] This is probably also the reason, or excuse, for not having a freedom of information law at the federal level. This view may not be entirely accurate as the OSA was enacted to protect official secrets which are defined as documents, information or material which are classified. Nonetheless, this Act has created a culture in the political world where public officials are reluctant to share information due to the threat of prison sentences and large fines.[243]

Whether patients' medical records held by the government fall under the OSA is unclear. The most distinct cases of invasion of privacy involve those of breached confidence in connection with the doctor-patient relationship. Custodians and users of medical records are the only stakeholders who have made a declaration under the OSA and are authorised to manage and access these medical records. Medical records and their contents are private and personal information and therefore categorised as classified official documents and must be given a certain level of protection. Medical records are therefore classified as 'confidential' and their management has to comply with procedures for the management of classified documents. As a large amount of personal data is processed and stored by the government in public hospitals, thus rendering the government the biggest data user in the country, to exclude the government from the PDPA has legal implications. Borrowers such as researchers in public institutions, for example, who access these classified documents are also accountable for the safety and

[242] Lee, 'Limitations of the Personal Data Protection 4 Act 2010 and Personal Data Protection in Selected Sectors', 69.
[243] Rais Yatim, 'Freedom under Executive Power in Malaysia: A Study of Executive Supremacy', King's College London 1994), 384.

confidentiality during the period these documents are in their possession. Therefore, to have a definite exclusion of the Federal and State governments from the Act means that the government is not legally accountable and this leads to a general conclusion that data protection of medical records in Malaysia may not necessarily comply with existing regulations and laws.

Secondly, Section 2(1) of the PDPA states that the Act applies to anyone who processes, has control over or authorises the processing of any personal data in respect of 'commercial transactions'. The use of personal data in medical records in a public, subsidised, healthcare system may not necessarily involve a profit-making exercise, thus rendering it non-commercial. This limitation creates a legal implication as any processing of personal data in what are considered non-commercial activities would not be subjected to the PDPA and this therefore creates a *lacuna* in the law. The Act also fails to properly define what constitutes a 'commercial transaction' and while a private hospital may be profitable in nature, the public hospitals which rely on subsidies and provide a non-profitable margin with healthcare delivery as an exchange of service may be irrelevant. Thus, the PDPA does not extend to the largest provider of healthcare, thus rendering it ineffective as a mechanism to help patients access their medical records.

The PDPA is only applicable to private hospitals or clinics where the OSA does not apply and commercial transactions do. Other limitations of this Act include the lack of provision of remedies or compensation for the data subject. Although PDPA provides offences for failure to comply with the Act, there is no remedy for the data subject and thus no compensation if their data has been misused.

In many jurisdictions' data protection laws, any breach of privacy of data is punishable under both criminal and civil law. For example, Section 13(1) UK's DPA 1998 allowed data subjects

to claim compensation if they suffer damage or distress by any contravention of the Act.[244] The DPA 1998 has since been replaced by the UK General Data Protection Regulation supplemented by the Data Protection Act 2018. Therefore, it shows that the lack of remedies needs to be addressed to uphold the intent of the Act to protect the interests of those for whom it was enacted in the first place. Ironically, Section 42 of PDPA does provide the right for a data subject to prevent processing that is likely to cause stress or harm and a right to claim compensation from the data user who causes it. However, the Act does not specifically mention data in the form of medical records. This ambiguity leads to an extrapolation of whether 'data' as defined in the PDPA can be applied to medical records. Although it is theoretically correct to regard medical records as part of personal data, the law has so far failed to recognise a general right to access medical records to include the most used healthcare provider; public hospitals.

In Malaysia, the lack of other provisions and enforcement in the PDPA creates ambiguity for both data users and subjects. It appears that even with the enactment of the PDPA where data protection should be adopted in sectors including health institutions, the Act does not appear to cover all aspects of data protection that extend to medical records. However, there are general reporting obligations in the health sector that are not unique to data breach notification and may be relevant.

Other legislation may also be rendered ineffective as tools for patient access to medical records. Section 37(1) of the PHFSA mandates that private healthcare facilities and services must notify any unforeseen or unanticipated incidents to the Director General or any person authorised by him in that capacity. Relevant parties such as hospitals and clinics and their employees including doctors, nurses, pharmacists and dentists would have to resort to protecting the data

[244] Refer to *Llyod v Google* [2021] UKSC 50.

subjects' personal data by invoking the common law duty of confidentiality with the PDPA. As the Medical Act 1971 is silent on the duty of confidentiality, the Confidentiality Guidelines issued by the MMC in October 2011, which was after the PDPA was enacted, is considered the most comprehensive articulation of this obligation of health professionals. The Code of Professional Conduct and Guidelines of Confidentiality also emphasise the obligation of the doctor to maintain the confidentiality of the patient's medical information.[245] . The MMC can exercise its disciplinary jurisdiction and imposes punishments on the doctors if they breach this duty.[246] To date, doctors in Malaysia are not under any obligation to keep medical records in any specified form or manner.[247] This duty allows patients to feel assured in disclosing personal information to their doctors. This is established in the International Code of Medical Ethics which states that 'doctors have the duty to preserve in absolute secrecy, all he or she knows about a patient due to the confidence entrusted to him or her'.[248]

The main weakness of the PDPA comes down to the fact that it does not extend to the largest data user in healthcare; the Malaysian government which owns the public health institutions. This renders PDPA ineffective as a reference to help patients access their medical records. The lack of clarity heightens the double standards that may apply to both doctors and patients working in and attending private institutions because neither the Medical Act 1971 nor the MMC provides and authorises such actions. The PHFSA regulates private facilities and provides licensing of the management of private hospitals, nursing homes and maternity homes to ensure that services provided by these premises meet standards, particularly in relation to

[245] Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Confidentiality* (2011).

[246] Medical Act 1971, s 30(1). Disciplinary punishments include (i) order the name of such registered person to be struck off from the Register; (ii) order the name of such registered person to be suspended from the Register for such period as it may think fit; (iii) order the registered person to be reprimanded; or (iv) make any such order as aforesaid but suspend the application thereof, subject to such conditions as the Council may think fit, for a period, or periods in the aggregate, not exceeding two years.

[247] Malaysia Medical Association, 'Code of Medical Ethics ' (2001), accessed 5 May 2019.

[248] World Medical Association, 'International Code of Medical Ethics' (1949), accessed 13 February 2021.

consultation and procedural fees, but does not cover data protection policies or right to access medical records. Thus, Malaysia not only has a two-tier healthcare system, but also a complex regulatory configuration.

## 2.8 The role of regulatory bodies in the management of patient access to medical records

Since independence from the UK in 1957, the government has provided health and health-related services with public income subsidies.[249] Healthcare in Malaysia is regulated by the MoH which provides a nationwide healthcare system that runs a two-tier model composed of both a subsidised public healthcare system, comparable to the NHS in the UK and a co-existing and thriving private healthcare system. The MoH is the internal regulator of its own facilities and staff while the private sector is regulated by the PHFSA under the Private Medical Practice Control Division of Medical Practice (CKAPS) and the Unit Private Medical Practice Control of the MoH which control and monitor private healthcare facilities and services.

The MMC and the MoH constitute the regulatory structure overseeing Malaysian medical practitioners and healthcare services. Each regulatory body has its own disciplinary committee, but the MMC is the only body to impose sanctions on doctors when necessary. Its responsibilities include registering and regulating medical practitioners who wish to practise in Malaysia and ensuring that medical practice meets reasonable and acceptable standards. In disciplining those who fail to meet the required standard, the Code of Professional Conduct 2019 requires the establishment of a Preliminary Investigation Committee (PIC) to investigate complaints or information on disciplinary matters (Part III in Disciplinary Procedures).

[249] Wan Abdullah and Nik Rosnah, 'Medical Regulation in Malaysia: Towards and Effective Regulatory Regime', 97.

Pursuant to the objectives set up by the Act, public hospitals under the administration of the MoH are bound to follow the Medical Act 1971. Doctors in the public sector are regulated under various tiers of regulatory structure: the state level, the ministerial level (Minister of Health) (MoH) and the level of the Public Service Department. There are Inquiry Committees to examine ethical and disciplinary matters about doctors in the public service in which the Board of Inquiry is usually conducted at the state level. The MMC can discontinue, suspend or re-establish registrations of medical practitioners depending on the outcome of disciplinary matters. Table 2 shows the regulatory domain on patient access to medical records in Malaysia and how the relevant actors are involved and operate to fill the regulatory space that they occupy.

**Table 2-1: Regulatory domain on access to medical records in public and private sector**

| Policy domain | Regulators and actors | Main functions | Statutory provisions, guidelines and circulars governing main functions |
|---|---|---|---|
| Access to Medical Records in Public Sector | Direct State Regulator: MoH<br><br>Medical Practitioners in the public sector under three tiers:<br>State Level<br>Ministerial Level<br>Public Service Department | Acts as an internal regulator of its own facilities and is the main regulatory actor which acts as the major employer of health professionals and provider of healthcare services | Medical Act 1971<br>Medical Regulations 1974<br><br>Health Circulars and Guidelines:<br>Management of Medical Records in Hospitals and Institutions (2010) |
| | Core Regulatory Body: MMC | Register medical practitioners intending to practice in the country and ensure medical practice is of reasonable and acceptable standards | MMC Ethical Codes and Guidelines:<br>Code of Professional Conduct<br>Good Medical Practice<br>Confidentiality<br>Medical Records and Reports |
| Access to Medical Records in Private Sector | Direct State Regulator: MoH<br><br>Private Medical Practice Control, Division of Medical Practice (CKAPS)<br>MCMC | Control and monitor private healthcare facilities and services | PHFSA 1998<br>Private Healthcare Facilities and Services Regulations 2006<br>Personal Data Protection Act 2010 |

## 2.9 Ethical codes and guidelines on medical records and patient access

### 2.9.1 Guidelines on Medical Records and Medical Reports 002/2006 (MMC)

The current practice in Malaysia for patients to have access to information in medical records is through medical reports (see Section 1.2) and is enforced by the MMC. Clause 2.5 of the MMC Guidelines on medical records and medical reports states:

> It is unethical for a practitioner to refuse to provide a medical report and the patient has every right to complain to the Medical Council of any such refusal or undue delay. If, in his considered opinion, the practitioner has strong reasons to deny such a report, he should be able to justify his decision and inform the patient. The withholding of medical reports because of failure of the patient to settle professional and healthcare facility and services fees and bills is unethical.

The 2006 Guidelines also contain details on the handling of medical records and medical reports. According to Clause 1.12:

> A patient's medical records are the property of the medical practitioner and the healthcare facility and services which hold all rights associated with ownership. They are also the intellectual property of the medical practitioner who has written them and also belong morally and ethically to the practitioners and patient.

This clause clearly states that the ownership of medical records lies with the medical practitioners and healthcare institutions. Paradoxically, despite stating the intellectual property of the information belongs to those who created it (the doctors), it also says that morally and ethically, it belongs to the patients and the doctor, therefore contradicting the assertion of the doctor's ownership. The records will be in many forms including the doctor's clinical notes, referral notes to other specialists or the patient's laboratory results, histological reports and imaging records whose ownership rights are not defined. The clause relates to different types of information including data relating to patients that ethically and morally belong to the patient. For example, lab and radiological reports or diagnoses and a summary of the patient's history and professional judgement including possible differential diagnoses are documented

in the medical records based on the clinician's observations, are the intellectual properties of the clinician. Thus, it is clear from this clause that despite stating that the information morally and ethically belongs to both parties, medical practitioners and hospitals hold 'all rights' associated with ownership. This is one of the most important restrictions on patient access to medical records, leaving only the legal avenue of obtaining a court order. Perhaps due to the ambiguity and lack of definition of patients' rights, the MMC and other regulatory actors fit this practice around their main stakeholders' interests, the doctors.

Other factors support the restriction of medical records for patient access including the requirement for a court order, but the question of ownership may be one of the biggest. On the matter of physical ownership, Clause 1.11 of the Guidelines of the Medical Records and Reports states that medical records should not be taken out of the healthcare facility, necessitating a copy to be made under an order of the court. However, Clause 1.15 also states that:

> The patient may be entitled to access medical records as part of the contract between him/her and the medical practitioner, for various purposes, ranging from the need to seek the second opinion, to seek further treatment elsewhere, or for litigation. This privilege is also extended with the patient's consent to the patient's appointed agents.

If the patient or their agent requests access and is refused after all other avenues have been explored, they may resort to civil action and order of discovery. The use of 'may be' entitled to access despite stating that the information morally and ethically belongs to the patients (Clause 1.12) is because a patient's medical records are the property of the doctor and healthcare providers who hold 'all rights'.[250] This entitlement must also follow a purpose (albeit a different type of purpose from 'legitimate purpose and in good faith').[251] It is not an

[250] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.12.
[251] Ibid cl 1.7.

automatic right, despite patients having 'the right of such access' to their medical records. The Clause is also incongruous because it validates circumstances in which access is refused and patients may then resort to civil action. Therefore, within the MMC Guidelines alone, contradictions exist in which patients do not have absolute or automatic access, despite having moral and ethical ownership of medical records.

Given the absence of a definition, the reference to morality and ethics in the recommendations appears to have been included for rhetorical purposes to appease the parties involved during the drafting of the Guidelines. The use of rhetorical statements in healthcare policy and regulation has been discussed and can function to clothe arrangements with the appearance of legitimacy.[252] But on closer inspection, the language is ambiguous, uncertain and operates to protect non-patient interests.[253] This is more likely if the references to morality and ethics are not well-aligned with the real values or beliefs of the clinicians and lack legal legitimacy. While rhetoricalism is not studied in depth for this thesis, the proposition that a policy statement should be aligned with the values of its users is an important factor when considering reforms in later chapters (see Section 7.3.1). On the other hand, it could just be a case of poor drafting by the MMC and a lack of diligence.

It is also stated in Clause 1.9 that medical records are confidential, and they are not to be handled or carried by the patient. Therefore, even with EMR, which other countries such as the US have used as a platform for patients to directly access medical records in real-time, Clause 1.9 has prohibited such a practice and is another barrier to patient access even if the technology becomes universally available in Malaysia. The Clause states that '[i]t is acceptable to label

[252] Jill Russell and others, 'Recognizing Rhetoric in Health Care Policy Analysis' (2008) 13 Journal of Health Services Research & Policy 40.

[253] Similar observation was made in Horton's 2017 article on NHS whereby he claimed that the NHS regulatory framework was set up but regulatory practice was portrayed and followed differently as observations are not representative of what occurs in practice.

the medical records on the cover "Not to be handled by patient"' which may simply suggest that health professionals can issue a prohibition. It could also be enabling behaviour on the part of doctors to continue 'owning' the records. Thus, the Guidelines show that health professionals issue instructions indicative of ownership and control over the records.

### 2.9.2 Guidelines for the Management of Patients' Medical Records for Hospitals and Medical Institutions Circular 17/2010

The MoH, via circular 17/10, has produced the Guidelines for the Management of Patients' Medical Records for Hospitals and Medical Institutions. Implemented in 2010, it only affects institutions with paper-based medical records although several government hospitals have adopted EMR. It states that access to medical records must be approved by the Director of the hospital and Clause 9 states that the patient is not allowed to make copies of their own records, albeit a court order. Otherwise, a patient can only request information in the form of a medical report (see Section 1.2) but not necessarily the entire record (Clause 11).

### 2.9.3 Good Medical Practice Guidelines 2019

Lastly, the Good Medical Practice Guideline 2019 issued by the MMC also states that a patient or their agent may demand medical records for various purposes which include the need to seek a second opinion or to pursue further treatment and to search for a basis for litigation (Clause 4.7.8). Doctors must respond promptly to requests for comprehensive medical reports from patients or the next of kin (Clause 4.7.10). However, where medical records are sought by third parties such as employers, insurance companies or solicitors, doctors must not disclose them in the absence of the patient's consent. Despite this, I would argue that the current practice that appears to be implemented by the MMC is to allow patients to have access to medical reports, but not to medical records as the legal sanctions are clearly written in the Guidelines.

The differences between the two were described in Chapter 1 with medical reports created and written by the clinicians at the time of a patient's request.

## 2.10 Summary and discussion on guidelines

The guidelines and policies discussed above agree that medical records belong to the healthcare provider and are accessible to patients.[254] However, there are restrictions to patients accessing medical records in both the Guidelines and the Circular. The physical ownership of medical records lies with the hospital and access must be approved by the Director of the hospital.[255] The physical property and the intellectual input of the patient's condition are created by the healthcare institutions and entered by the staff and the patient can only request information on their health through a medical report, which only includes selective information. The MMC acknowledges that patients should have access to their medical records for 'legitimate purpose and good faith'.[256] The MMC also extended the statement that patients have the right to know what personal information is recorded and who has access to it and expect the records to be accurate (Clause 1.7).[257] In addition, the MMC Guidelines endorse resorting to civil action if access is refused, while the Ministry's Circular states that any access must be approved by the Director of the hospital and only copies are allowed following a court order. Therefore, these documents create ambiguity over patient access to medical records due to the contradiction that exists and the practice resulting from these inconsistencies. The authorities that issued these regulations are also governed differently; the MoH is a direct state regulator that acts at both

[254] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*.
[255] Ministry of Health, *Guidelines for the Management of Patients' Medical Records for Hospitals and Medical Institutions*
[256] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.7.
[257] Ibid cl 1.7.

state and ministerial levels while the MMC is a state-sanctioned body, with its powers granted by Parliament and agents of direct government regulation.

Therefore, without a court order, requesting medical reports rather than records is the usual pathway for patients to access their health information. I would argue that the current practice of allowing access to medical reports but not records is endorsed by the Minister of Health and is a compromised position for patients. Doctors are obliged to provide comprehensive medical reports when requested by patients or their next of kin without unreasonable delay. When medical reports are sought by third parties such as employers, insurance companies or solicitors, doctors cannot disclose them without the patient's consent. However, despite these liberties, these practices do not translate to automatic and immediate granting of access to the original medical records.

As the only recourse for the release of these documents is through civil action despite the Guidelines and Circular clearly recognising patients' right, this translates to soft law. The medical profession and authorities continue to refuse these applications, requiring an application to the court. Essentially, legal processes could be ignorant of the specific concerns and values of those involved in the conflicts, especially the non-state actors that the law governs.

### 2.11 Ambiguity over the ownership of the data in medical records

Ownership relates to who may access and grant access to both the physical form and the information on medical records. The information in medical records belongs to the patients but this leads to an inherent absurdity in placing the onus of protecting the right of access on patients who most consistently are deprived of ownership and access. The patient has the legal right to know the contents of their own medical records and access them. To protect this right,

it is important to recognise the gap that exists in Malaysia and for it to be addressed by regulatory bodies and non-state actors.

This ambiguity in ownership is evident in a Malaysian law case which influenced the common law of Malaysia on access to medical records. In *Nurul Husna, Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*,[258] Nurul Husna (the patient) suffered severe and irreversible brain damage at Selayang Hospital, a public hospital owned and operated by the government of Malaysia. The second complainant, the patient's mother, worked as a radiologist for the Malaysian government. Both plaintiffs alleged that the doctors and nurses who attended to the delivery and the post-natal care of the first plaintiff were negligent and this led to the injury sustained. Nurul Husna claimed that she had spastic quadriplegia, cerebral palsy and a major global development delay as a result of her injuries. At first, the defendants disputed responsibility. The applicants had written to Selayang Hospital requesting copies of the medical records, but the defendants similarly refused to provide them. The complainant requested an order for a copy of an internal investigation report to be released. Following the discovery order and the preparation of the internal investigation report, the defendant chose not to dispute liability but refused to register a formal admission of liability. As a result, the court allowed the plaintiffs' application pursuant to O. 27 r. 3 of the rules of Court 2012[259] for a finding of liability against the defendants and an evaluation of damages to be accessed.

In the matter of access to medical records, the court held that:

> The ownership of a patient's medical record vests with the physician or hospital as the case may be. However, the physician or hospital must deal with the medical records in the best interest of the patient. The patient has an innominate and qualified right of access to medical records and there is a corresponding general duty on the part of the physician or hospital to disclose the patient's medical records to the patient, agents, medical advisers or legal advisers. The

[258] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.
[259] Ibid para I.

> physician or hospital may refuse to disclose partly or wholly the medical records to the patient in certain limited circumstances, such as, but not limited to, situations when such disclosure would be detrimental or prejudicial to the patient's health in that the information is likely to cause serious harm to the physical or mental health of the patient or of any other individual contained in the medical records; or when such disclosure would divulge information relating to or provided by an individual, other than the patient, who could be identified from that information. When the circumstances giving rise to such qualification for refusal to disclose does not present itself and when the request for disclosure is reasonable, having regard to all the circumstances, the physician or hospital shall give copies of the medical records to the patient upon payment of reasonable copying charges.[260]

The right of access to a person's own medical records in *Nurul Husna* was also determined where the Court stated the following:

> The prevalent common practice among medical professionals and hospitals is to refuse to give copies of patient's medical records unless ordered by the court to do so. This has necessitated the filing of applications by patients seeking court's intervention to order production of the medical records. In most cases, when the application comes for hearing, the respondent throws in the towel and agrees to produce copies of the medical records sought. In a handful of cases, there is resistance and the court determines the issue to order production. This guarded conduct of the medical professionals and hospitals has caused patients to incur avoidable costs and delays by filing originating processes for an order for discovery of their medical records[261].

In *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*[262] the High Court held that the refusal of medical records to the claimant is a breach of pre-action discovery findings and made an award for aggravated damages. This was a case where, despite reminders, the defendant doctors and hospital provider failed to comply with the order for pre-action discovery of the plaintiff's medical records. The claim for medical negligence arose from an injury sustained during birth at the defendant hospital. The court held that the defendants' conduct fell below the standard expected of government hospitals and awarded aggravated damages for disobeying the High

[260] Ibid para [1].
[261] Ibid para [13]
[262] *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*. See para 1.

Court's decision in *Nurul Husna* and failing to follow the provisions of the earlier order. The records were only delivered to the plaintiff after he filed before the cause of action expired. The plaintiff was also awarded costs. This demonstrates that the Court will not excuse a defendant's disregard for the Court order by awarding damages to the plaintiff. Despite the findings in *Nurul Husna*, patients still need a court order to access their medical records, even if it is not for litigation purposes. The Court awarded the plaintiff aggravated damages for delay by the government hospital in releasing the records.

Evident from these two cases is that there is a general acceptance in Malaysia, at least in the legal system, that ownership of medical records rests with the doctors or the hospital authority although patients' right to access are acknowledged. However, the exercise of this right is not routinely practised. With no legal enforcement, doctors and hospitals have restricted patient access to medical records although such action is a non-acceptable standard of conduct under the MMC Guidelines and at common law.

Similarly, an article in the Journal of the American Medical Association also sits in a similar position to Malaysia when it comes to ownership of medical records, in that their guideline also states that medical records are fully owned by the doctors and hospitals:

> Clinicians, as owners of the paper records they maintain, can give or sell medical records to other clinicians for treatment purposes and block access by anyone except the patient. Patients have rights of privacy and access to their records, but neither federal nor state law explicitly extends property rights to patients. For instance, patients do not have the right to sole possession or to the destruction of their original records.[263]

Due to the nature of medical records, there is a contradiction between the ownership of the information and the 'physical ownership' which belongs to the healthcare provider. The

[263] Mark A Hall and Kevin A Schulman, 'Ownership of Medical Information' (2009) 301 The Journal of the American Medical Association 1282, 1282.

competing property rights of doctors coupled with the patient's privacy rights, although convoluted, are still explicit and were upheld by the court in the cases illustrated above. The Malaysian courts maintain the moral argument that patients have the right to access their medical records. From the courts' lens of ownership, the doctor or hospital provider are the owners of the patient's medical records. The patient has an indefinite and limited right of access to medical information and the doctors have a corresponding duty to respect this right, although they may withhold information deemed detrimental to patients. This duty is a moral responsibility for doctors but this value is not sufficiently embedded in professional culture for doctors to abide by it and by extension work for the best interests of their patients.

## 2.12 Conclusion

This chapter has discussed the arrangements that underpin patient access to medical records in Malaysia. It has a two-tier system that is governed separately by different Acts and policies. The first resounding factor that impedes wider patient access is the different guidelines and policies governing different sectors of the healthcare system but not addressing medical records explicitly, resulting in inconsistencies and double standards.

The MMC Guidelines do touch on medical records ownership. Despite being created as a regulator by the Medical Act, it does not have the legal standing to enforce its Guidelines. Certain provisions seem to be impossible to implement and doctors are generally reluctant to hand over medical records to patients, likely due to fear of litigation and not being part of routine practice. This may be considered prejudicial to patients since the healthcare provider is aware that the medical records could be used against them. The MMC allows a loose network of protection under its Guidelines and therefore is considered to be non-prescriptive. However,

despite the explicit statement in the MMC Guidelines, enforcing this authority is only going to be effective if internal and external regulatory cultures change.

I have also discussed the legislation on data protection in Malaysia and whether the PDPA has the potential to impose the statutory right for a patient to have access to their health information and whether 'personal data' can be extended to medical records. Although it is theoretically correct to regard medical records as part of data privacy, the law has failed to recognise the general right to access medical records to apply to the most used healthcare provider; public hospitals. However, aspects of the PDPA which are consistent with the English common law undermine the doctor's 'therapeutic privilege' as withholding disclosure by data users should be inimical to the interests of the data subjects although such privilege exists to avoid harm or distress to patients. This is further discussed later in the thesis.

Access and control of medical records also revolve around the question of ownership. The law on ownership of information is poorly developed in most jurisdictions and Malaysia is no exception. In general, the assumption is that the information in the medical record belongs to the patient, but the interpretation and opinion recorded into it belong to the doctors. Where there is no special access statute, the only way a patient can get information from their medical records is to bring a suit against the doctor or hospital and get a court order. Therefore, this practice relies on the court's decision as a court order seems to be the only sure route. Unfortunately, patients have to become litigants to obtain access. It may also exacerbate conflict in society and cause patients' health to deteriorate and lead to a distrust of institutions. This practice creates the vicious cycle in which healthcare providers thus associate direct access with litigation and are reluctant to endorse the notion of wider access. This is further exacerbated by court orders as a means to grant access to medical records for litigation purposes and doctors associate access to records with further legal scrutiny and thus are likely to act more defensively.

Despite Malaysia being one of the first countries in Southeast Asia to pass a PDPA (2010), there is no freedom of information law at the federal level. In this chapter, I argued that the PDPA does not offer robust protection to granting wider patient access to medical records. The growing accessibility of EHRs across hospitals in Malaysia raises questions about whether they can be made available for patients and whether patients should be able to control provider access. However, unlike in the UK, there is still no sight of legislation in relation to universal right to access, right to rectification and right to restriction on the use of personal data in healthcare. The UK position in comparison with Malaysia is explored in the next chapter.

# Chapter 3. Patient access to medical records in the UK: A background and comparative analysis with Malaysia

## 3.1 Introduction

This chapter focuses on the legal position on patient access to medical records in the UK and a comparative analysis with Malaysia. I intend to compare these legal and regulatory frameworks due to the historical link between Malaysian law and English common law. The Malaysian PDPA 2010 was also based on the UK's DPA 1998. Despite these links, legal and historical connections may not be enough to compare or solve key questions on patient access, especially when patriarchal culture continues to persist in the doctor-patient relationship in Malaysia. However, the UK laws have existed for a long time and have likely attained some milestones that Malaysia would be well to recognise, particularly concerning the discussions and problems that arise during the creation and implementation of rules on patient access to medical records.

This chapter outlines the procedures which allow parties to obtain hospital records in the UK, a right enshrined in the Access to Health Records Act 1990 and the Data Protection Act 2018. The comparative analysis will enable a better understanding of the legal prospect of widening patient access in Malaysia. Combined, these goals are in accordance with the government's intention to transform Malaysia into a knowledge-based economy and society.[264] Malaysia's reliance on the English common law in the absence of written law, the recognition of UK right to patient access and the UK's DPA experience make the UK a prime example.

The Malaysian PDPA 2010 was based on the UK's DPA 1998, albeit with modifications to adapt to local circumstances. DPA 1998 has been repealed and has been replaced with the DPA

[264] Indrajit Banerjee and Mustafa K Anuar, 'The Promise and Pitfalls of Leapfrogging - the Malaysian Experience' (1999) 1 Asia Pacific Media Educator 133, 138.

2018. Issues such as the principles of access in the PDPA should be given attention in Malaysia. It is important to study these policies as the many different facets, scopes of policy and ways of implementation may be confounding factors to successful implementation not only in Malaysia but in other countries as well. I will consider whether the similarities can be used to argue for wider patient access in Malaysia using a reform approach based on the template developed in the UK, rather than building an entirely new system. The only caveat is that there is a need to be cautious as these are two different countries with potentially crucial differences and variables.

I have mentioned the core role of regulators in the Malaysian healthcare setting whereby the MMC sets and enforces certain standards of ethical conduct including matters pertaining to patient access to medical records. As an equivalent regulator of MMC, it is important to discuss the role of the General Medical Council (GMC) in the UK and its evolution towards a regulatory body that emphasises safety and quality of care. In the earlier part of Chapter Two, I elaborated on how the MMC regulates patient access to medical records in Malaysia using its guidelines but also discussed the limitations of its role. In order to explore and compare the equivalent regulatory bodies between the two countries, the GMC's role within its jurisdictions will be discussed in this chapter. Therefore, in framing what best practices for regulatory reform in Malaysia using the UK as a comparative platform would look like, it is reasonable to consider and compare first, the legal links between the UK and Malaysia.

### 3.2 Legal links between the UK and Malaysia

As a developed country with established legislation coupled with a more overarching engagement with stakeholders, it would be best to consider the UK legal policy, recognising

the positive outcomes and learning from the weaknesses and drawbacks to anticipate the challenges of reforming the system of patient access to medical information in Malaysia. This may help the Malaysian government to pinpoint specific legal issues and effective regulatory strategies.

Malaysia has an independently functioning Constitution and is open to developing its bodies of law by drawing on persuasive sources of authority such as English law; the legal framework on patient access was configured by Malaysian lawmakers using English law. The legal proximity between the two jurisdictions carries advantages for this study as the existing MMC Guidelines are inadequate to provide such protection. Parliament should have the capacity to grant the authority, which reflects good practice, but this has to suit Malaysian needs both culturally and legislatively.

The UK's position on patient access is relevant for two reasons. First, the applicability of the English common law and equity in Malaysia as a Commonwealth state is governed by the Civil Law Act 1956, section 3(1) and other provisions which provide that courts in Malaysia must apply the common law and rules of equity of England in the absence of a written law. Common law means that 'there is no comprehensive compilation of legal rules and statutes. While common law relies on some random statutes which are legislative decisions, it is largely based on precedent, meaning that the judicial decisions have already been made in similar cases'.[265] Until 31 December 1984, the Judicial Committee of the UK Privy Council was the highest Court of Appeal in Malaysia under Article 131 of the Federal Constitution.[266] From 1 January 1985, appeals to the Privy Council were abolished and the Malaysian Federal Court became

[265] The Robbins Collection, 'The Common Law and Civil Law Traditions' (2010) <https://www.law.berkeley.edu/wp-content/uploads/2017/11/CommonLawCivilLawTraditions.pdf>, accessed 20 May 2021.

[266] Ibrahim Ismail, 'Judicial Certainty and Creativity: An Evaluation of Stare Decisis' (2004) 8 Jurnal Undang-Undang dan Masyarakat 79, 100.

the highest court in Malaysia.[267] Since then, reference to English law has been made when deciding local cases, although English law is not binding in the local courts.[268] However, it still has relevance as a persuasive authority in Malaysia. Thus, developments in English law since the establishment of the Malaysian Federal Court in 1985 do not have a direct binding effect on Malaysian courts, but the fact that they are still referenced makes English law a significant influence on courts in Malaysia.[269] As long as the Malaysian Constitution's supremacy is respected and adhered to, there is still absolute freedom for Malaysian law to develop while using English law as an influence.

### 3.3 Legislative developments in the UK (Past and Present)

The UK's Access to Health Records Act (AHRA) 1990 grants comparable access right to manually held medical records exclusively and the DPA 1998 which replaced the DPA 1984 established a distinction between computerised and non-computerised documents by granting patients particular access right to computerised medical records. The 1984 Act applied exclusively to electronic records. Hence, the right to access personal data is embedded in both the DPA and the AHRA. Individuals have a right to access their health records and, in limited circumstances, to access information on other people. The DPA 2018 domesticated the GDPR which came into effect on the 25th May 2018 and amended the DPA 1998.[270] It was the primary

[267] Kwame Sundaram Jomo and Sau Ngan Wong, *Law, Institutions and Malaysian Economic Development* (University of Chicago Press 2008).
[268] SM Nordin and LP Keng, 'An Overview of Malaysian Legal System and Research' (*Hauser Global Law School Program,* 2016), accessed 8 June 2019.
[269] Mohamad and Trakic, 'The Reception of English Law in Malaysia and Development of the Malaysian Common Law', 129.
[270] Aaron Kulakiewicz, Tom Powell and Elizabeth Parkin, *Patient Health Records: Access, Sharing and Confidentiality* (07103, (2022).

component of English law's framework for the protection and access to confidential information.

The DPA 2018 is the current regulation which provides data subjects with a right to access their personal data.[271] There were previously eight principles that underpinned the DPA 1998, which were developed further by the EU GDPR and as part of the revised version of the GDPR, were made a part of the UK law. However, after Brexit (withdrawal of the UK from the European Union), the UK was required to comply with the UK GDPR which became law on 1 January 2021. The 2018 legislation consists of six principles, unlike the eight principles in DPA 1998.

According to Part 3 of Chapter 2, which lists the data protection principles of the DPA 2018, any individual or organisation engaged in the handling of personal data is required to ensure that all such data conform in: (1) lawfulness, fairness; (2) purpose limitations; (3) data minimisation; (4) accuracy; (5) storage limitations; (6) integrity and confidentiality (security).[272] According to the DPA 2018 Act in Section 205 (1), a 'health record' consists of ' a) data concerning health and b) has been made by or on behalf of a health professional in connection with diagnosis, care or treatment of the individual to whom the data relates'. For this reason, the terms 'health record' and 'personal data' can be used interchangeably. The processing must not be in breach of any existing legal restrictions such as the common law of duty of confidence, particularly data in the form of health records. Although the Act did not replace the common law framework of confidentiality and access, the statute remains an addition to it, albeit a dominant one. Thus, should any changes be made in widening access to

[271] Data Protection Act 2018.
[272] Ibid s 35(1).

Malaysian health records, they must take this as a consideration and become the principal building block or fundamentals to any such changes.

The AHRA predates the current DPA but was passed after the DPA 1984. Originally a private member's bill,[273] the government decided to support it, subject to necessary safeguards, because its provisions were entirely consistent with the Department of Health's policy on access to records. The Under-Secretary of State for Health said the Department's consultation exercise states that there was a clear balance of opinion in support of a right of access.[274] The Bill intended to change the dynamic of the doctor-patient interaction so that the doctor would be encouraged to tell the patient more about their illness and that the patient's medical issues and suggested treatments would be more correctly reflected in the records.[275] It was claimed that medical records are needed to maintain patient care and are used by doctors and other health professionals to help them with diagnosis. Their primary purpose was to record what is in the best interest of patients as there may be circumstances in which the uncontrolled disclosure of information may cause harm or distress.[276]

The Campaign for Freedom of Information advocacy group also claimed that individuals should have the right to access information that affects them and allows them to make decisions about their life. These concepts were at the heart of the UK government's openness policy on freedom of information, which advised the public about their right to information, giving patients a new sense of independence and encouraging them to take more responsibility for their own health.[277] Since the Freedom of Information Act was introduced in 2000, the Campaign for Freedom of Information has fought for the public's right to know and has assisted

[273] UK parliament, 'Access to Health Records Bill' (1990) <https://api.parliament.uk/historic-hansard/commons/1990/feb/23/access-to-health-records-bill>, accessed 20 January 2020.
[274] Parliament of UK, *Data Protection and Access to Personal Health Information*, (1993).
[275] Ibid.
[276] Ibid.
[277] Ibid.

thousands of activists, journalists and the public in submitting freedom of information (FOI) requests and challenging unreasonable refusals to release information.[278] However, to be more specific, the Freedom of Information Act, which recognises the right to access information held by a public authority, in itself does not give people access to their own personal data (information in medical records). Requests for personal information are achieved through a different procedure under the data protection Subject Access Request (SAR).[279] (see Section 3.4).

The main piece of law governing access to information in England and Wales is the Freedom of Information Act 2000 (FOIA), which came into force in January 2005. The Freedom of Information (Scotland) Act (FOISA) 2002 is exclusive to Scotland. Under the Act, requests may be made by letter or email and the public body is required to advise the applicant within 20 working days if it has the requested information in its possession[280]. The Act also includes all government departments and publicly sponsored companies as well as all the information they hold and is retroactive, meaning it applies to events that occurred before the Act was passed. Although the Ministry of Justice is in charge of the FOIA, it works to promote more transparency by putting pressure on public servants to implement the Act. [281] The ICO administers and enforces it, with the Information Tribunal adjudicating its applicability and the consequences of a breach.[282] The Scottish Information Commissioner is in charge of upholding the Freedom of Information (Scotland) Act (FOISA) 2002.[283]

---

[278] Facebook, *Campaign for Freedom of Information* ; Freedom of Information Act 2000.
[279] Information Commissioner's Office, *Right of Access* .
[280] Freedom of Information Act 2000, s 10(1).
[281] Lord Chancellor and Secretary of State for Justice by Command of Her Majesty, *Government Response to the Justice Committee's Report: Post-Legislative Scrutiny of the Freedom of Information Act 2000* (2012).
[282] Information Commissioner's Office, *What Happens When Someone Complains* .
[283] Scottish Information Commissioner, *FOI Law in Scotland* .

The FOIA was a significant turning point for information access in general and the protection of personal information in particular in the UK. By strengthening the right to access already established under the DPA, the Act has contributed to increasing the openness and transparency of how government and public sector information is used. However, based on the goals of autonomy, dignity, liberty and security, a person's right to information privacy is also a personal freedom.[284] Thus, the Freedom of Information Act is relevant in this thesis as it highlights movement and direction of change, which enhances access to information held by a public authority and also personal information in the UK.

For Malaysia, with widespread access to the internet and increasing health literacy,[285] there will inevitably be more requests for information, including access to medical records. This discussion on the UK legislation provides an adoptable approach should Malaysia widen its access to medical records. Therefore, plans must be in place to anticipate and address unique concerns should Malaysia follow the same path through the introduction of new legislation similar to that in the UK.

### 3.3.1 Restriction of access

The AHRA was introduced to give patients the right to access their health records in manual form. It grants patients a statutory right of access to manual health records dating back to 1 November 1991, subject to certain exceptions.[286] 'Health records' are defined in section 1(1) of the Act as documents which:

[284] Human Rights Act 1998See Guide to Article 8.

[285] Norrafizah Jaafar and others, 'Malaysian Health Literacy: Scorecard Performance from a National Survey' (2021) 18 International Journal of Environmental Research and Public Health 5813.

[286] National Health Service in Scotland Management Executive, 'Access to Health Records Act 1990' (1991) .

a) consist of information relating to the physical or mental health of an individual who can be identified from that information or from that and other information in the possession of the holder of the records

b) has been made by or behalf of a health professional (i.e., clinical doctor or nurse in connection with the care of that individual)'.

Under Section 5(1) of AHRA, 'health professionals' can deny patient access to their records due to the likelihood of 'serious harm to the physical or mental health of the patient or any other individual'. However, the Act does not define or indicate the circumstances which might constitute 'serious harm' which is open to broad interpretation.[287] The Act also focuses on patients' views and acknowledges that an interpretation of the doctor-patient relationship 'pre-supposes a measure of agreement as to what should be kept secret and what should be disclosed'.[288]

The Data Protection (Subject Access Modification) (Health) Order allows for a partial exemption from the rules of the Data Protection Act that give data subjects the right to access personal information that is held on them[289]. Data relating to the physical or mental health or condition of the data subject ie patients may be denied access to their medical records if the information contained in them will endanger the patient's or another person's physical or mental health or condition.[290] Whilst there is some overlap between this exception and the right under common law to deny access when it is not in the patient's best interest, the DPA has exceptions. Whether or not accessing the record would harm the patient or another person must

[287] Morris Bernadt, Lucy Gunning and Margot Quenstedt, 'Patients' Access to Their Own Psychiatric Records' (1991) 303 British Medical Journal 967, 967.
[288] David Carman and Nicky Britten, 'Confidentiality of Medical Records the Patient's Perspective' (1995) 45 British Journal of General Practice 485, 485. Access to Health Records Act 1990
[289] Data Protection (Subject Access Modification) (Health) Order (S.I .No 413) 2000. See explanatory note. The note is not part of an order.
[290] Ibid s 5(1).

be determined by a suitable health professional as it involves the practice of clinical judgement.[291] Because of the confidentiality principle, healthcare providers will also be prevented from disclosing to patients any information in their medical records that may identify a third party.[292] However, disclosure is permitted where the recognised third party is a health professional who has contributed to the patient's medical records in their professional capacity or has been engaged in the care of the patient.

On similar note, Section 5(1), the AHRA 1990 also recognises that there are circumstances in which information should be withheld. Any part of the patient's data that would reveal details that, in the opinion of the data holder: (1) would be likely to seriously harm the physical or mental health of the patient or any individual; or (2) relate to a third party identifiable to the patient must not be accessed unless the third party consents to the disclosure or is a health professional who has provided the details in their professional capacity.[293] Here the AHRA is concerned with 'data' as defined in the Act and found in patient records. Under Section 3(2)a of the AHRA, the applicant is entitled to access the whole record and, therefore, must be permitted access to the record itself. Where the applicant's right of access is limited to a certain part of the record, the Act states that the applicant should be given access to an 'extract' setting out the relevant part. It would appear that this enables the holder of the record to give the applicant access to the relevant part of the actual record itself or the copy of the relevant part.[294] Section 6(1) states that if the applicant considers that any information to which she or he has been given access is incorrect, misleading or incomplete, a request may be made in writing for rectification.[295]

---

[291] Ibid
[292] Ibid
[293] Access to Health Records Act 1990, s 5(1).
[294] Ibid s 3 (2).
[295] Ibid s 6(1).

Finally, it is important to remember that the DPA is primarily concerned with data collection and processing, but it also has privacy functions because it protects informational privacy. Although the term 'privacy' does not appear anywhere in the Act, it was enacted to conform to the European obligation on the right to privacy. There seems to be a potential point of debate here. Perhaps there is no need for healthcare providers to explain why they are denying patients access to their medical records. Although withholding appears to contradict the DPA's transparency principle, openness in certain cases may eliminate the necessity for information to be kept in the first place. There could be a role for withholding the data in the medical records but at the same time being open and transparent on why the data is being withheld. If patients are aware that information was missing or understand the reasons why it was not made available, they may be able to deduce the nature of the suppressed information. Patients may be able to discern the nature of the suppressed information if they are aware that information was omitted or concealed.

In *McGinley and Egan v UK*,[296] the European Court of Human Rights (ECtHR) held that the question of access to documents relating to danger to which the applicant has been exposed was sufficiently and closely linked to the privacy and family lives to raise an issue. The applicants had participated in nuclear tests conducted by the UK at Christmas Island. They later requested contemporaneous records of those tests in the context of their applications for service disability pensions. Their request was refused. The ECtHR did not find a violation of Article 8. Article 8 of the European Convention of Human Rights requires an effective and accessible procedure to enable such persons to seek all relevant and appropriate information.[297] It is possible that in certain circumstances, the comparable exemptions in the DPA or under common law might be found incompatible with the patient's right under Article 8 and Article

[296] *Mcginley and Egan v UK* [1998] 27 EHRR 1.

[297] European Court of Human Rights, *Handbook on European Law Relating to Access to Justice* (Council of Europe 2016).

10.[298] Article 8 of the ECHR provides a right to respect for one's private and family life and Article 10 concerns freedom of expression.

The DPA also attempted a balance between protection and access. The balance reflects not only the common law tension between the right of confidentiality, the right of access and the public interest, but also the apparent conflict between Article 8's right to privacy and Article 10's right to receive and impart information.

### 3.3.2 Balance between liberal access and restriction of access

The disclosure of medical records by healthcare professionals to patients when requested has become a legal requirement governed by the DPA and AHRA. However, the two statutes are limited in scope. The DPA applied exclusively to electronic records, while the AHRA was restricted to manual records after November 1991. Access to manual records before that date is governed by common law.[299] Before then, patients relied on the limited access rights of the common law as there was no statutory requirement for doctors in the UK to grant the patient access. However, in *R v Mid-Glamorgan Family Health Services Authority, ex parte Martin* the Court of Appeal did not recognise an innominate common law of the right to access medical records.[300] The patient was unable to rely on the AHRA because it expressly prohibited access to records made before 1 November 1991. This was because the records were not stored electronically. Had they been so, he would have been permitted to access under the DPA (Subject Access Modification) Health Order 1987.[301]

In this case, the applicant, a 46-year-old man with a chronic psychiatric history had requested judicial review of the local health authorities' reluctance to unconditionally reveal all of the

---

298 European Convention Human Rights 1959.

299 *Regina v Mid Glamorgan Family Health Services Authority, Ex Parte Martin* [1995] 1 All ER 356.

300 Civil Procedure Rules 1998; *Regina v Mid Glamorgan Family Health Services Authority, Ex Parte Martin*

301 Dermot Feenan, 'Common Law Access to Medical Records' (1996) 59 The Modern Law Review 101, 101.

documents in his medical records. Despite the Court of Appeal upholding the earlier claim that there was no right at common law to secure patient access to medical records, stating that Article 8 ECHR had not been breached, the High Court dismissed the appeal on the grounds that the applicant's claim had to be decided under common law. The judge did not recognise patient access and refused access on the grounds that a doctor or health authority, as the owner of medical records, was entitled to deny access as disclosure could be detrimental to the patient. He rejected the applicant's submission that there was an 'access principle' based on Article 8 EHCR and the applicability in English law of the concept of a doctor's fiduciary duty to release medical records to patients. The Court held that even though the applicant had some rights to access his medical records, those rights were restricted in cases where doing so would put his or others' health at risk. As the owner of the records, the healthcare providers should be able to assess whether the information was likely to be harmful.[302] Mr Martin appealed.

Although the Court of Appeal rejected his appeal, the judges made remarks favourable to a patient's right of access to medical records:

> There is no good reason for doubting either that a right of access does exist or that it is qualified to [the extent at least expressed now in the statute section 5(1)(c)]. The record is made for two purposes which are relevant here: first, to provide part of the medical history of the patient, for the benefit of the same doctor or his successors in the future; and, secondly, to provide a record of diagnosis and treatment in case of future inquiry or dispute. Those purposes would be frustrated if there were no duty to disclose the records to medical advisors or to the patient himself, or his legal advisers, if they were required in connection with a later claim. Nor can the duty to disclose for medical purposes be limited, in my judgement, to future medical advisers. [303]

The Court held that patients do not have the right to access their medical records if such access is likely to endanger their physical or mental health although it did not accept that a health

[302] Ibid 109.

[303] *Regina v Mid Glamorgan Family Health Services Authority, Ex Parte Martin* .

authority had absolute rights to manage medical records without limits. The doctor's duty, likewise, the authority's, was to act at all times in the best interests of the patient.

The Honourable Kirby, in his extra-judicial statement on the matter, argued:

> The most that can be derived from *Regina v Mid Glamorgan* is that it is an indication, at a high level of the English courts and outside the obligations of statute, that an assertion by a medical practitioner of absolute ownership and control of 'his' medical records concerning a patient, is unacceptable to the common law of England. [304]

Thus, *Mid-Glamorgan* fails to provide a conceptual explanation of ownership, yet a doctor or health authority has the right to refuse access to a patient's medical records on the grounds that doing so would be harmful to the patient. I would characterise the common law approach as paternalistic as it seems to be routine practice throughout the common law, especially relating to treatment, diagnosis, and advice. Legislative endorsement of medical paternalism based on detriment is debatable, and despite DPA being enacted several years later; according to the provision in Section 2(2) of DPA 2018 on the 'serious harm test' the Act is imbued with paternalistic values. This may be in line with the common law position on therapeutic privilege, as access can be denied when the information can be detrimental and cause serious harm to the patient or others (see Section 3.4). Therefore, the ultimate decision to allow or restrict access remains with the doctors.

Based on these cases, it can be seen that access to medical records can be restricted if the doctor believes that any revelation would cause substantial injury to the patient's physical or mental health.[305] The information in the medical record is the material about the patient, but the records itself is still the doctor's or hospital's property, according to the courts. The doctor has the ultimate responsibility to act in the best interest of the patient and to justify the disclosure

[304] Michael D Kirby, 'A Patient's Right of Access to Medical Records' (1995) 12 Journal of Contemporary Health Law & Policy , 98.
[305] Refer to *Montgomery v Lanarkshire Health Board* [47].

of information as detrimental to the patient's health in certain circumstances. Although the law allows patients the right to access their medical records, the court must first assess the factors that should be considered before medical records is disclosed on a case-by-case basis. [306]

### 3.4 The law and regulation today

Today, how individuals and populations access and utilise information, including information pertaining to healthcare, is rapidly changing and yet in Malaysia, legislation tends to lag behind these changes.[307] The DPA 2018 updates the data protection laws and complements the UK General Data Protection Regulation (GDPR).[308] The Act, which took effect on 25 May 2018, supplements the UK's data protection legislation with the GDP (EU) 2016/679. The Data Protection, Privacy and Electronic Communications (Amendment) (EU Exit) Regulations 2019 was secondary legislation passed under the EU Withdrawal Act to retain the regulations contained in the EU's GDPR and create a domestic data protection law.[309]

According to the UK Information Commissioner, Elisabeth Denham:

> The previous Data Protection Act, passed a generation ago, failed to account for today's internet and digital technologies, social media and big data. The new Act updates data protection laws in the UK [… and] provides tools and strengthens rights to allow people to take back control of their personal data.[310]

The Regulation makes several changes to subject access requests (SAR). Exemptions to restrict access exist and can be applied as it is stipulated in the right of access to health data processing. However, the exemption only applies if complying with the right of access would likely cause

---

306 Feenan, 'Common Law Access to Medical Records', 110.

307 Nurul Izzatty Ismail, 'Adoption of Hospital Information System (HIS) in Malaysian Public Hospitals' (2015) 172 Procedia - Social and Behavioral Sciences 336.

308 Information Commissioner's Office, *Guide to the General Data Protection Regulation* .

309 The Data Protection, Privacy and Electronic Communications (Amendments Etc) (EU Exit) Regulations 2019.

310 Information Commissioner's Office, *An Overview of the Data Protection Act 2018* .

substantial harm to a person's physical or mental health. For health data, this is known as the 'serious harm test'.[311] This exemption is used if the person is a health professional or received an opinion from an eligible health expert that the serious harm test for health data has been met during the last six months.[312] The exemption might also apply to a SAR that was invoking paragraph 2(1) of Schedule 3, Part 2 of the DPA 2018.

Patients must have free access to their medical records in most cases, including when a patient authorises other parties such as a solicitor to access them through SAR. The Access to Medical Reports Act 1988 will apply if the application is for the creation of a medical report or for the interpretation of information that had been included in a medical report. Both require the creation of new data that is outside the scope of the GDPR and SAR. In certain cases, a fee may be charged but an existing medical report or record will be provided for free. A reasonable charge may be paid for a SAR if the application is plainly unreasonable, but these circumstances are unlikely. If an individual receives information through a request for subject access (SAR) and subsequently requests a copy of the same material within a short period, the application could be considered 'excessive'. In this case, the organisation could pay a reasonable premium based on the administrative costs of providing additional copies or declining requests.[313]

However, these changes and implications influence the wider landscape of allowing patients access to their medical records and this falls back to what is in the best interests of patients, as discussed in Part Two of the Ethical Analysis (see section 5.2.2.1). Several ethical considerations must be taken into account and further elaborated in the next part. For example, more information may boost patient understanding and confidence, but may also give patients

311 Data Protection Act, s 2(2).

312 Information Commissioner's Office, *Exemptions* .

313 British Medical Association, 'Access to Health Records' (2018) <https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/access-to-health-records>, accessed 22 June 2019.

an uncomfortable sense of responsibility. Providing written information could widen the existing gap in access to healthcare and have unanticipated opportunity costs as doctors and patients have divergent perspectives on how much information should be shared and when (see Chapter 4).

### 3.4.1 Introducing the Duty of Candour in the UK

In the UK, the healthcare professions recently introduced the 'duty of candour' to patients and their families in cases where an incident has occurred, whether or not this led to an unfavourable outcome.[314] The responsibilities include giving an adequate explanation, an apology and taking corrective action and are part of this duty to disclose and encourage transparency and honesty as well as improve patient safety and professional discipline. [315] The greatest challenge to implementing such a duty within the profession is fear of lawsuit, a central theme in the impetus to provide patient access to medical records in Malaysia, as has been suggested in this thesis.

In Malaysia, the duty of candour does not have a statutory footing in healthcare and therefore this is an important difference to discuss here as a comparison to the UK, especially as the duty of candour campaign has its roots in issues of access to records for family members as well as litigation. The most notable case in the UK was in 1990, in which a child's father pursued an investigation after the untimely death of his child at the age of 10, exposing 35 separate criminal offences including falsification of patient's medical records and documentations.[316] The European Court of Human Rights stated:

[314] Oliver Quick, 'Duties of Candour in Healthcare: The Truth, the Whole Truth, and Nothing but the Truth?' (2022) 30 Medical Law Review 324.
[315] Ibid.
[316] *William and Anita Powell v the United Kingdom* [2000] 30 EHRR CD 152 (European Courts of Human Rights).

> As the law stands now….doctors have no duty to give parents of a child who died as a result of their negligence a truthful account of the circumstances of the death, nor even refrain from deliberately falsifying records.[317]

Since this landmark case, tort law has long emphasised the responsibility of candour, but it is important to recognise the recent creation of a legislative duty in the medical field.[318] A statutory responsibility of candour was suggested after inquiry into the Mid Staffordshire NHS Foundation Trust exposed numerous substandard cases, demonstrating a culture lacking in openness and transparency which led to unfavourable outcomes for patients. The regulatory system then was unable to discover the causes for Stafford Hospital's substandard patient care, which led to patient injury and death. In other studies, health care practitioners' non-disclosure rates after medical errors were estimated to be between 24% and 30%.[319] Two months after the Francis report was published on the scandal of the Mid Staffordshire NHS Foundation Trust, a new contractual duty of candour came into effect for the NHS in England, suggesting that the unacceptable scandal that had materialised had resulted in an urgent emphasis to take action.

As part of the legal mandate in the UK, the Health and Social Act 2008 Regulations 2014 established candour as a legal requirement. This obligation, which initially extended to all 'health services bodies' came into force in November 2014.[320] Regulation 20 of the Health and Social Act states 'A health service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity'.[321] It places an obligation on 'registered persons' to be forthcoming with information about care and treatment with patients or representatives. The obligation to be candid serves as a legal necessity to reflect the need to be honest about harm. While harm is

---

[317] Ibid.

[318] Vinita Shekar and Peter A Brennan, 'Duty of Candour and Keeping Patients Safe' (2020) 38 Surgery 637, 637.

[319] Stuart M White, Nicky Deacy and Sandeep Sudan, 'Trainee Anaesthetists' Attitues to Error, Safety and the Law' (2009) 26 European Journal Anaesthesiology 463.

[320] The Health and Social Care Act 2008 .

[321] Ibid

discussed in other parts of the thesis (Section 4.3.2.2), the legislation defines qualifying thresholds in which a notifiable safety incident is described as 'any unintended or unexpected incident that in the reasonable opinion of a healthcare professional could result in, or appears to have resulted in a) death of the service user, b) severe harm (defined by the National Patient Safety Agency as a permanent lessening of bodily sensory, motor, physiologic or intellectual functions), moderate harm or prolonged psychological harm'.[322] Failure to comply with the requirements of the legislation is considered a criminal offence.

A joint guidance of the General Medical Council with the Nursing and Midwifery Council was also created. Titled 'Openness and honesty when things go wrong: The professional duty of candour (GMC Guidance)',[323] it became the first of its kind in the world. The recommendations include detailed suggestions on how to disclose and apologise, fulfil the obligation to be truthful and open, and support a culture of learning by disclosing harmful instances and near-misses.[324] Another review report was created by the Royal College of Surgeons England analysing the threshold for the duty of candour and the incentives for care organisations to be candid.[325]

The duty of candour and its process have not been introduced without some debates. While many considered that the process of full transparency protects patient autonomy and might prevent a legal action, there were suggestions that an admission of fault and liability with a risk of legal or disciplinary proceedings would facilitate blame culture and defensive practice in medicine.[326] Professor Don Berwick concluded in his report in 2013 that statutory duty was

[322] Ibid para 8.
[323] General Medical Council, *Openness and Honesty When Things Go Wrong: The Professional Duty of Candour* (2015).
[324] Ibid.
[325] David Dalton and Norman Williams, *Building a Culture of Candour* (2014).
[326] Shekar and Brennan, 'Duty of Candour and Keeping Patients Safe', 638.

unnecessary as existing guidance and professional regulation were adequate, while the legislation would lead to defensive documentation and excessive bureaucracy.[327] Evidence has, however, shown that increasing transparency does not increase litigation, but reduces the cost through active decompensation.[328] However, the Francis Report's most important recommendation to introduce a statutory duty of candour advised that:

> Unless steps are taken to evidence the importance of candour by creation of some uniform duty with serious sanctions available for non-observance, a culture of denial, secrecy and concealment of issues of concern will be able to survive anywhere in the healthcare system.[329]

### 3.4.2 The General Medical Council

As earlier mentioned, the General Medical Coucil (GMC) is an equivalent regulator of MMC. The current GMC was established by the Medical Act 1983. Under the Act, one must be registered to practise medicine. In addition, the GMC was charged with: setting medical education standards including regulating university courses; revalidation (in which licensed doctors in the UK undergo an annual professional appraisal); and investigating and acting on concerns about doctors. Although the GMC is a statutory body, it has a powerful self-regulatory professional component. Section 35 of the Medical Act 1983 provides the GMC with the authority to determine 'in such a manner as the Council thinks fit, advice for members of the medical profession on standards of professional conduct or on medical ethics'. The subsequent sections of this Act relate to the GMC's powers to regulate doctors' 'fitness to practise' and 'professional conduct'.[330] It is enforced on doctors by requiring them to follow professional

---

[327] Don Berwick, *A Promise to Learn - a Commitment to Act: Improving the Safety of Patients in England*, (2013), 34.

[328] Ronald M Stewart and others, 'Transparent and Open Discussion of Errors Does Not Increase Malpractice Risk in Trauma Patients' (2006) 243 Annals of Surgery 645.

[329] R Francis, *The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Hc 898-111*, (2013).

[330] Medical Act 1983 Medical Act, (1983) General Medical Council, 'Good Medical Practice - Ethical Guidance' <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice>,

standards as a continuing condition of registration, and registration is compulsory in order to practise as a qualified medical practitioner. As mentioned, another major role of the GMC is it is responsible for licensing and revalidating all registered practising doctors in the UK. The GMC outlines the standard of practice in the guidance on Good Medical Practice. Thus, if a doctor does not comply with the requirements, fitness to practise can be challenged and compromised, which may impose limits on the doctor's capacity to practise or, in the most severe circumstances, remove the doctor from the medical register.[331]

The current role of the GMC expanded beyond registration of doctors following previous scrutiny and underwent a drastic change in response to the Bristol inquiry report,[332] which led to several reforms including the concept of self-regulation being replaced with professional regulation and introduction of medical revalidation; it was scheduled to review the performance of all doctors between 2012 to 2016 and took on responsibility for medical education and practice. In 2011, the Department of Health invited the Law Commission in England to review the complex legislation which was published three years later, concluding that the regulatory systems that included nine health professional regulators overseeing the practice of 1.4 million workers were bureaucratic, inflexible and not fit for purpose.[333] The governance of the GMC and its composition were also overhauled, reducing its council in size as well as appointing 'lay' or public members as opposed to exclusively medical practitioners. Currently, 40% of the members are public or 'lay' people. [334] Audit and data are collected locally and nationally to

accessed 11 June 2023. The General Medical Council publishes a number of guidance including Confidentiality and Consent.

331 General Medical Council, *The General Medical Council and Professional Standards Authority: Proposed Changes to Modernise and Reform the Adjudication of Fitness to Practise Cases* (2014), 9.

332 Abigail Tazzyman and others (2019) 13 Regulation & Governance 593, 593.

333 Kieran Walshe, 'Medical Regulation: More Reforms Are Needed' (2014) 349 British Medical Journal .

334 Steve Dewar and Belinda Finlayson, 'Reforming the GMC' (2001) 322 British Medical Journal 689, 689.

study and understand variations in practice and research evidence is attained to improve and sustain performance.

#### 3.4.2.1 The GMC's position on patient access to medical records

In response to the legal and professional demands for safeguarding patient access to medical records, the mechanisms that govern the practice are partially included in the GMC Patient Confidentiality Guidance, which refers to the Data Protection Act in attempting to prevent personal data and information from being divulged to third parties.[335] Therefore, access according to the GMC is a practice linked to patient confidentiality, in which the GMC Guidance on Confidentiality: Good Practice in Handling Patient Information, para 131 states:

> Patients have a right to access their own health records, subject to certain safeguards. You should respect, and help patients to exercise, their legal rights to have access to, or copies of, their health records.[336]

A doctor has a basic obligation to provide copies of medical records to his or her patient under long-standing medical ethical principles, with some exceptions. The GMC Ethical Guidance for doctors in paragraph 59 states:

> Patients, including children and young people, have a legal right to see their own medical records unless this would be likely to cause serious harm to their physical or mental health or to that of someone else.[337]

To date, there is no mention of patient access to medical records aside from the two statements above. Therefore, the GMC, in comparison to the MMC in Malaysia, has placed less emphasis on this subject as a right to obtain medical records, as opposed to access to confidential information that belongs to oneself in the DPA. Indeed, with the explicitness of the DPA, it is probably not necessary for the GMC to reiterate this concept as an absolute right because access

---

335 Data Protection Act 2018.

336 General Medical Council, *Confidentiality: Good Practice in Handling Patient Information* (2017).

337 General Medical Council, 'Good Medical Practice - Ethical Guidance'.

to medical records is enshrined in clarity under the data protection legislation in the UK while remaining ambiguous in Malaysia.

## 3.5 A comparative analysis with Malaysia

The similarities and differences between the UK and Malaysian statutory laws may be able to justify or improve restrictions that inhibit wider patient access in Malaysia. This comparison creates a platform to consider reform as an institutional template and minimises the need to overhaul the medico-legal system. So far there are no studies that claim the UK has the best practice worldwide. In framing the best practice for regulatory reform, should wider access be justified for Malaysia, the similarities and differences and the advantages and disadvantages between practices should be analysed.

### 3.5.1 Difference in regulatory bodies

Firstly, there is a difference in the regulatory bodies in the UK and Malaysia. In the UK, The ICO is an independent body with the responsibility to uphold information rights, data privacy for individuals while maintaining the interest of the public and promoting openness by public bodies.[338] The ICO is a public authority established under the law of the UK under Section 7 (1) of the UK DPA 2018.

In Malaysia, Section 47 (1) of the PDPA 2010 appoints the PDP commisioner to carry out the functions and powers assigned to the Commissioner under the Act on such terms and conditions as they think desirable.[339] It works under the Personal Data Protection Department, which is part of the Multimedia Ministry of Communications and Multimedia Commission (MCMC).

[338] Information Commissioner's Office, *About the ICO* .

[339] Shumaila Hussain Shahani, 'Overview of the Comparative Analysis' (2020), accessed 8 May 2022.

The Department was founded on 16 May 2011, after Parliament enacted the PDPA. Therefore, the PDPA 2010 is regulated centrally by the Ministry whilst the UK counterpart is regulated independently, illustrating a more state-centric approach to the regulation in Malaysia (see Chapter 7).

Other regulatory bodies in the UK which were absent in Malaysia included the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission; these were combined to form the Care Quality Commission (CQC), which went into full operation in 2009. The CQC has mandated all healthcare organisations in England, including the NHS, to register. According to the Health and Social Care Act of 2008, CQC has the authority to prosecute, sanction, and secure changes in addition to gathering information from reports of health and safety events.[340] The Health and Safety Executive (HSE) in the UK, on the other hand is the national independent regulator for health and safety that encompasses private or public owned health and social care settings in the UK governed by the Health and Safety (Enforcing Authority) Regulations 1998.[341] Besides these regulators, there are also professional legislative bodies aimed at ensuring that health and social care professionals are maintaining appropriate standards. Professionals are required to register with the relevant body to practise in the UK. All practising doctors, irrespective of place and nature of work, are regulated by the GMC. The HSE has a Memorandum of Understanding[342] with the GMC which is an agreed framework for cooperation and collaboration between the two organisations. The Memorandum lays out the corresponding roles and duties and describes mechanisms for efficient liaison relationships; the main duties are to maintain an up-to-date register of professionals and to set and maintain standards for education, training and conduct as well as

[340] Elizabeth Parkin, *The Care Quality Commission*, (2020).
[341] Health and Safety (Enforcing Authority) Regulations 1998.
[342] Health and Safety Executive, *Memorandum of Understanding between the Care Quality Commission and the Health and Safety Executive* (2017).

investigate when these standards are not met or when a professional's fitness to practise is in doubt.[343] To date, there are no specific statements or guidelines in relation to patients themselves accessing medical records in the CQC or HSE.

The difference between the MMC and the GMC will be illustrated in the table below:

[343] Ibid.

**Table 3-1: Difference between GMC and MMC in the UK and Malaysia**

| Regulators | Main Functions | Council Members | Statutory Provisions | Fees | Provisions from Guidance/Guidelines |
|---|---|---|---|---|---|
| MMC: Core Regulatory Body under Ministry of Health | Register medical practitioners intending to practise in the country<br><br>Ensure medical practice is of reasonable and acceptable standards<br><br>Accredit medical institutions locally and abroad | President: Director General of Health Members: Fully registered healthcare professionals (33) | Section 3 of Medical Act 1971 | Annual budget from the Ministry of Health | A patient's medical records are the property of the medical practitioner and the healthcare facility and services which hold all rights associated with ownership. They are also the intellectual property of the medical practitioner who has written them and also belong morally and ethically to the practitioners and patient (Clause 1.12 of MMC Guidelines of Medical Records and Reports)<br><br>The patient may be entitled to access medical records as part of the contract between him/her and the medical practitioner, for various purposes, ranging from the need to seek a second opinion to seeking further treatment elsewhere, or for litigation. This privilege is also extended with the patient's consent to the patient's appointed agents (Clause 1.15 of MMC Guidelines of Medical Records and Reports) |

| | | | | | |
|---|---|---|---|---|---|
| GMC: Independent Regulator | Exercises their functions to protect, promote and maintain the health and safety of the public<br>Regulates and sets the standards for medical schools<br>Responsible for licensing and revalidation system for all practising doctors in the UK | Healthcare professionals and lay members (10) | Medical Act 1983 | Funded by fees paid by doctors from membership | Patients have a right to access their own health records, subject to certain safeguards. 'You should respect, and help patients to exercise, their legal rights to have access to, or copies of, their health records' (Para 131 of GMC Guidance on Confidentiality)<br>Patients, including children and young people, have a legal right to see their own medical records unless this would be likely to cause serious harm to their physical or mental health or to that of someone else (Para 59 of GMC Ethical Guidance) |

### 3.5.2 Difference in ideology: Ownership

A central difference between the two countries is the question of ownership of medical records. In Malaysia, the hospital providers or doctors that generate or maintain the record are regarded as the ultimate 'owner' of medical records.[344] Regulation 44(1) of PHFSA states that the doctor owns the paper on which the information is written as '[a] patient's medical record is the property of a private healthcare facility or service'.[345] Medical records are classified as confidential official documents. It is unusual that the PHFSA applies only to the private health sector when healthcare provision should be subjected to the same moral values. This is especially of concern if the medical records are no longer simply a tool for healthcare providers to record their impressions, observations and instructions but rather serve many purposes beyond direct healthcare (see Chapter 1). This proprietary right confers not only the right of possession but also the right to determine who may have access to the record and for what purpose. It is also held that the provider's ownership is subject to the patient's right regarding the information contained in the record. The need for strong protection of patients' rights to access further complicates the analysis of who owns health information. Knowledge could be owned and protected as intellectual property via contract, patent or copyright, but it has long been assumed under common law that information itself cannot be owned or stolen.[346] This may require the state authorities to revisit the concepts of ownership (see Chapter 7).

In *McInerney v Mcdonald*, a Canadian case, the Court held that the owner was not a mere custodian:

> The medical record is an unusual type of property because physically it belongs to the hospital and hospital must exercise considerable control over access, but

[344] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*.
[345] Private Hospital and Other Private Healthcare Facilities Regulations 2006, reg 30(2).
[346] Amy L McGuire and others, 'Who Owns the Data in a Medical Information Commons?' (2019) 47 Journal Law of Medicine and Ethics 62, 62-64.

> th patient and others have interest in the information in the record……. I find it unnecessary to reify the patient's interest in his or her medical records and, in particular, I am not inclined to go so far as to say that a doctor is merely a 'custodian' of medical information. [347]

This case illustrates that a voluntary act should be the prime reason for such action leading to the disclosure of medical records by doctors to their patients as opposed to a legal obligation. This case also emphasises that doctors' ownership of medical records does not confer unqualified power and absolute right over patients' medical records.[348] However, these actions must be practised under the tenet of the doctor's duty to act in the patient's best interest. The DPA does not address the patient's right of ownership of the record itself but rather the information contained in it. Wecth proposed his own definition of ownership in medical records, although this is not a representation of the law in UK:

> The plain fact is that the patients have a proprietary interest in their own medical records. At the very least the information contained in medical record is the property of the patient. But for the patient, the information would not exist. To require the assistance of counsel to get such records unfairly and unnecessarily burdens a patient who is trying to obtain what is rightfully his.[349]

Waller and Alcantra claim that:

> Even under the traditional rule, however, no person or entity can be truly said to 'own' patient-identifiable information if what is meant by ownership is the ability to exercise complete sovereignty over the information- to disclose, sell, destroy, alter or determine who shall access to it at will.[350]

In Malaysia, there has been a lack of discussion about the ownership of medical records despite the explicit statement indicating that the physical ownership lies with the hospitals or providers (see Chapter 2). The extract from Wecth is a concise provision addressing the issue that patients

---

[347] *Mcinerney v Macdonald* [1992] 93 DLR . See page 10.

[348] Kathleen Liddell, David A Simon and Anneke Lucassen, 'Patient Data Ownership: Who Owns Your Health?' (2021) 8 Journal of Law and Biosciences 1, 38.

[349] CH Wecth, 'Patient Access to Medical Records: Yea or Nay?' (1978) 6 Legal Aspects of Medical Practice , 8-10.

[350] AA Waller and OL Alcantara, 'Ownership of Health Information in the Information Age' (1998) 69 Journal of American Health Information Management Association 28, 29.

are allowed to have access to their medical records as it is believed that the records both morally and ethically belonged to the patients, but this has not been reflected in practice.

Malaysia's concept of ownership is firstly ambiguous and lacks a clear definition. It is further worsened by a statute that does not cover this protection. As a clinician who practised in Malaysia, I proposed that the main differences between the two countries are the lack of awareness and consideration of patients' right to access in Malaysia which leads to the absence of discussions or dialogue on this matter. This is further evident by the lack of scientific references pertaining to this matter in my thesis.

The UK's position on the concept of right to access enables access to records unless doing so may result in harm. Despite the DPA 1998 which has been superseded by the DPA 2018, individuals still have legal right to apply access to health information about them as Subject Access Request. [351] In the UK, the ownership of medical records by the healthcare provider, although given legal right to access, is not absolute whereas in Malaysia, although medical records are also owned by the healthcare provider, the attitude to ownership, lack of awareness to access and lack of clear definition of right to access, lead to more authoritative ownership by the healthcare provider. This is further exacerbated by the lack of legislation to provide legal rights to the patient, leading to the court for such access. This forms the backdrop of the difference between Malaysia and the UK. It implies that ownership perhaps will require a definition that is all-encompassing but addresses the perspective of both parties. Addressing this conundrum will form the basis of my recommendation in chapter eight.

[351] Information Commissioner's Office, *Right of Access*.

### 3.5.3 Caveats in the legal mechanisms

There are a few caveats in the legal mechanisms between these two countries that highlight the differences in access to medical records. In this section, I will discuss the differences and deficiencies of the Malaysian legislation compared to the UK.

The UK has other statutory rights that are related to access to medical records such as the AHRA 1990 and the Medical Reports Act 1988. For the UK, Section 5(1) of the AHRA recognises that there are circumstances in which information should be withheld. Access to any part of the patient's notes must not be given if it would, in the opinion of the holder, cause serious harm to the physical or mental health of the patient or anyone else or relates to an identifiable third party. In Malaysia, Section 42 of the PDPA does provide the right for a data user to prevent processing that is likely to cause stress or harm. Therefore, both countries cover the right to personal data, but Malaysia's PDPA does not specifically mention data in the form of medical records whereas the UK DPA 2018 refers to it in Section 205(1) as a 'health record'.

Secondly, the PDPA only applies to the private sector, while the UK laws apply to both the public and private sectors. The DPA extends both to documents kept by the NHS and to private health records and records kept by health practitioners in their own practices.[352] Malaysia's PDPA was not drafted to cover healthcare and public institutions but rather for commercial transactions. This renders the UK's legislation more robust as it has rules specifically applied to the healthcare sector and the parallel connection with the DPA makes it more relevant to medical records.

In comparison, Malaysia has only guidelines from the MMC and MoH which are not binding. The Circular from MoH does not recognises the patients' right to access medical records even

[352] British Medical Association Guidance, *GPS as Data Controllers under the General Data Protection Regulation* (2018).

though the MMC Guidelines states that patients should have access to medical records for 'legitimate purpose and good faith; know what the personal information is recorded and who has access to them; and expect the records to be accurate'[353] under Clause 1.7. Therefore, there is a discrepancy between the MoH and MMC as both publish guidelines for doctors who practice under both authorities.

Thirdly, the relationship between the UK's duty of candour and the medico-legal landscape in Malaysia remains unknown due to the lack of literature as well as dialogue pertaining to this matter. The above-mentioned discussion highlights the parallel concerns in access to medical records: more openness and transparency that could lead to unnecessary distress, defensive medicine, defensive reporting and learning through fear of prosecution or public infamy.[354] In Malaysia, there is no explicit law and recognised duty of candour as there are no statutory provisions targeted for the government's healthcare facilities and services. However, doctors in Malaysia have an ethical duty to inform their patients if an unfavourable incident or outcome occurred and to provide an explanation and apology. The Medical Council Guidelines on Good Medical Practice state:

> If a patient has suffered serious harm for whatever reason, the doctor should act immediately to put matters right. The patient must receive a proper explanation on the short and long term effects. When appropriate, the doctor should offer words of comfort and empathise with the patient and family members, which is a social etiquette. Such an act is not an admission of guilt or liability.[355] (clause 11.3-11.4)

The Good Medical Practice guidelines therefore promote the doctors to 'put matters right'[356] by explaining potential side effects as well as consolation from serious harm, but fail to mention 'open disclosure' in the face of medical errors. To date, there has been no published report on

---

353 Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.7.
354 Dalton and Williams, *Building a Culture of Candour*
355 Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Good Medical Practice* .
356 Ibid 17.

compliance or breaches of the above guideline and therefore, the act of candour, while endorsed, remains unfamiliar in the Malaysian landscape.

As the thesis has proposed earlier, patient access to medical records is restricted by doctors, most likely due to the fear of disclosing medical errors. Escalation to a potential lawsuit can be traumatic, impact on the doctor's reputation and be costly. It can be the very reason which contributes to the deterrent for doctors to promote candid disclosure, using different methods to include verbal and written explanation as well as in the form of access to medical records.[357] Compared with the UK, the legal duty to disclose will enhance the ethical values of honesty and transparency and promote autonomy, without clear evidence that it increases liability risk for healthcare professionals. Any reluctance to disclose may be outweighed by reinforcing the ethical principle that doctors must act in accord with their position of trust by sharing truthful accounts of information; and these accounts are also available in the form of medical records for patients to access.

## 3.6 Conclusion

The UK has more defined statutory rights relating to patient access and a clearer concept of legal right. The DPA gives individuals the right to access information in a computerised form and the AHRA in a non-computerised form. The UK is meticulous in considering all aspects from clearly defining the subject in question, to the responsibility and consequences to both healthcare providers (owners) and patients (ethical data owners) and its responsive role of adapting to the wave of technological advances. The combined effect of these Acts provides patients with a right of access to records compiled by health professionals in the UK where

[357] Lauris C Kaldijan and others, 'Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees' (2007) 22 Journal of General Internal Medicine 988.

ownership is not interrogated as the right have been clearly established and the role and limit of data subjects and users have been clearly delineated and defined.

A comparison with the UK illustrates the flaws in the Malaysian legal system. It recognises the statutory rights of patients to access medical records in which disclosure is generally allowed unless the disclosure is potentially detrimental to the individual's physical and mental health. However, the similarity ends there as the patients' rights are not codified in legislation as in the UK, but merely in a guideline lacking the necessary emphasis to allow better access to medical records. The effects of this will be explored in Chapter 7 along with recommendations. It is this combination of factors that results in recourse to a court order as the only method to secure access.

In highlighting these factors, this chapter has suggested that new legislation, while can influence practice may not be the best answer to address the ethical necessity of this issue. While legislation has its merits and should not be ignored, to reform certain competing values and beliefs, we need a mixed approach, as access to one's personal data, especially on health, is not solely a legal matter but an ethical and moral one (see Part 2). The integration of legal reforms and ethical changes will form the basis of my recommendations in Part 3 on widening patient access in Malaysia.

# PART TWO: ETHICAL ANALYSIS

# Chapter 4. Principlism and its application to patient access

## 4.1 Introduction

In the previous chapters, it was argued that the guidelines and legislation on patient access to their medical records in Malaysia are inconsistent and ambiguous and access is usually achieved through a court order.[358] This thesis aims to answer the question of whether wider access, defined as the automatic granting of access if requested by patients, should be granted without the need to obtain a court order.

To answer this question, we must first look at the desirable outcomes of widening access to patients. While specific legislation that grants automatic access would establish a mandated practice, it may also act as the lever to improve the regulatory challenges to ensure accountability and trust as well as improve patient satisfaction within the doctor-patient relationship. Before discussing the outcomes from an ethical perspective, I will first discuss the ethical theories, focusing on principlism in medical practice in the first section of this chapter and then its application in the second. Due to the conflicting values of different ethical principles which reflect the competing interests that inherently occur in the doctor-patient relationship, the discussion will be based on applied ethics underlying the themes based on both the patient's and doctor's perspectives. This chapter does not attempt to rigorously examine all ethical theories but provides sufficient background on how they can be applied to aspects of clinical practice before moving on to discussing patient access. Finally, these applications are then adapted to justify wider access to medical records in chapter five.

[358] Refer to *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

## 4.2 Overview of ethical theories

First, I will define bioethics, which can be distinguished from medical ethics. The word 'bio' covers all living organisms and therefore medical ethics is categorised as a branch of bioethics and emphasises the moral aspects of healthcare professionals and their duties.[359] Ethical theory is a theory of moral obligation using a framework in which a person can determine what they are morally obliged to do in a given situation. Of the ethical theories that have been most strongly associated with medical practice, I shall focus on three: utilitarianism, deontology and 135rinciplism strongly associated with medical practice.

### 4.2.1 Utilitarianism

The utilitarian or consequence-based theory focuses on the consequences of actions as the first step in analysing moral activity. According to this theory, which contemplates a balance between good and bad consequences, utilitarianism sees the rightness and wrongness of an action based on which action produces the greatest happiness for the greatest number of people.[360] There are two kinds of utilitarianism in contemporary debate: act and rule utilitarianism. [361] Act utilitarianism focuses on a particular act that will result in the greatest good for the greatest number of people. Rule utilitarianism considers the adoption of certain rules which will produce good consequences, in which a moral code is initially established, and individual actions are considered morally right if they accord with the rules.[362] While this theory concentrates on the value of well-being, there are concerns that it ignores justice for the minority of people involved in this process (see Chapter 5). The theory has also been criticised as outcomes cannot always be predicted and perceived happiness and desirable outcome are

[359] Varsha Gupta and others, 'An Introduction to Biotechnology' (2016) 23 Basic and Applied Aspects of Biotechnology 1.
[360] John Stuart Miller, *Utilitarianism* (Second edn, Longmans, Green and Co 1864).
[361] Lawrence C Becker and Charlotte B Becker, *Encyclopaedia of Ethics* (Routledge 2001).
[362] Ibid.

subjective. For example, is it morally acceptable to kill one person and distribute their organs to others who would die without them? According to some interpretations of this theory, such an act is not only permissible but morally obligatory although opponents of utilitarianism would argue that the harm caused to society by one death negates the overall benefits to others.[363]

In the context of access to medical records, this theory argues that unrestricted access provided to many individuals including patients, doctors and researchers may result in the greatest benefit to the largest number of people. However, the factors that influence patient access make utilitarianism too simplistic, as quantitative benefits alone are difficult to justify thus this will be discussed in the next two chapters. Overall, in utilitarian theory, the belief that 'the end justifies the means' suggests that the outcome will validate the means to achieve it ethically.[364]

### 4.2.2 Deontology: The Kantian formulations

Dentology is a non-consequentialist theory that stands in opposition to utilitarian theory. As the term 'deontology' from classic Greek means the study or science (*logos*) of duty (*deon*),[365] this theory claims that the same rule applies in all circumstances.[366] Kantian theory, the most-well-known deontologist theory proposed by Immanuel Kant describes morality as a supreme principle that provides a rational framework of universal principles and rules that guide and constrain every person.

Kant had three different formulations of the categorical imperative, although the first two are the best known. Wood quoted Kant which he claimed in the *Formula of the Law in Nature* that 'I ought never to act except in such a way that I can also will that my maxim become a universal

---

363 Beauchamp and Childress, *Principles of Biomedical Ethics*, 356-357.

364 Jharna Mandal, Dinoop Korol Ponnambath and Subhash Chandra Parija, 'Utilitarian and Deontological Ethics in Medicine' (2016) 6 Tropical Parasitology 5, 5.

365 Becker and Becker, *Encyclopaedia of Ethics*.

366 Ibid.

law'[367], which justifies all imperatives irrespective of our desires. Put simply, a person must always act the way they expect everyone else to act in the same situation, putting aside personal views or feelings. Secondly, in the *Formula of the End* one must 'act in such a way that you will always treat humanity whether in your own person or in the person of any other, never simply last a means, but always at the same time as an end'.[368] It puts the worth or the inherent value in the person who becomes the end and not the means to something else. The best example would be euthanasia where the judgement is based on the act rather than the consequence. Thirdly, in the *Formula of Autonomy*, one must 'act [such] that your will can regard itself at the same time making universal law through its maxim'.[369] The person's compliance with the law should be their own decision, not influenced or coerced by others. We are subject to the requirement of our maxims' conformity to the universal law through our own free will.[370] Should someone else be put in the same situation, they will act the same way as it conforms to the universal law, without any interest influencing the decision. For example, it is expected that people will not break promises, regardless of whether it is to their personal advantage or not.

This theory has been criticised as being inflexible, especially in the application of conflict between two or more moral people who disagree. According to Kant, the fundamental flaw of utilitarianism is that it judges actions based on the consequences, so could be argued that it might be incompatible with moral common sense. Kant's theory may not be able to resolve conflicts between two duties. For example, he argued for trust and the strict rejection of all lying whether the other has the right to know or not to know, including whether an innocent

367 Allen W Wood, *Kantian Ethics* (Cambridge University Press 2012)
368 Ibid.
369 Ibid.
370 Richard McCarty, 'The Formula of Autonomy ' (2014) <https://myweb.ecu.edu/mccartyr/GW/FormulaOfAutonomy.asp>, accessed 12 September 2020.

person might be harmed as a result of telling the truth.[371] To never tell a lie is one's duty and avoiding harm by not telling the truth is another duty. This becomes very relevant when we discuss later in this chapter, the roles of doctors as the information provider and appreciating the concept of a patient's right to know and not to know. This theory is later unpacked to justify wider access to improve the doctor-patient relationship in Chapter 7.

### 4.2.3 Utilitarian vs deontology

Both deontological and utilitarian principles may influence decision-making in healthcare. Tseng et al. argue that deontological ethics could be more patient-centred and that doctors would be obliged to 'do the right thing' irrespective of their own wishes.[372] Autonomy is also emphasised in deontological ethics,[373] which is a cornerstone of decision-making in healthcare. Utilitarian ethics are more society-centred and promote the greatest welfare for the maximum number of people, although the outcome of an action cannot always be predicted accurately.[374] As the two concepts differ, especially in emphasis on the outcome, conflict may occur between them.

These theories remain relevant today. For example, utilitarian ethics were applied during the Covid-19 pandemic in which many countries went into lockdown. One example is how to select patients who should receive a ventilator or balancing between social restrictions versus preventing death from Covid-19.[375] Deontological ethics was also applied; for example, medical professionals who decided not to have the vaccination will affect their own health

---

[371] Helga Varden, 'Kant and Lying to the Murderer at the Door. One More Time: Kant's Legal Philosophy and Lies to Murderers and Nazis' (2010) 41 Journal of Social Philosophy 403, 408.

[372] Po-En Tseng and Ya-Huei Wang, 'Deontological or Utilitarian? An Eternal Ethical Dilemma in Outbreak' (2021) 18 International Journal of Environmental Research and Public Health 1, 2.

[373] Philip J Balestrieri, 'Autonomy Versus Deontology' (2009) 18 International Journal of Obstetric Anesthesia 189.

[374] Mandal, Ponnambath and Parija, 'Utilitarian and Deontological Ethics in Medicine', 5.

[375] Julian Savulescu, Ingmar Persson and Dominic Wilkinson, 'Utilitarianism and the Pandemic' (2020) 34 Bioethics 620, 620.

while delaying herd immunity with social restrictions which may also cause harm to many individuals. [376] Despite these two theories being relevant in everyday clinical practice, the utilitarian principle places too much emphasis on quantitative benefits while the deontological principle does not address the complexity of human desires and self-interest and the balancing act that people perform daily. Hence, they cannot provide for the resolution of conflicts among two or more moral persons who disagree.[377] Next, I introduce principlism as a more relevant theory in answering my research question.

### 4.3 Principlism

Tom Beauchamp and James Childress' book *Principles of Biomedical Ethics* was first published in 1979.[378] It is one of the most popular textbooks on bioethics and is an ethical framework relevant to modern healthcare provision and widely taught in medical schools. The main features of the principlist model have been continuously modified by authors since the original publication of Beauchamp and Childress' approach, which makes it noteworthy.[379] To date, there have been eight editions of the book. McCarthy states that '[t]his reworking of their position has, I think, made it more resistant to the problems endemic to principlism generally and more inclusive of other features of the moral world that it had, initially, ignored'.[380]

[376] Carles Martin-Fumadóa and others, 'Medico-Legal, Ethical and Deontological Considerations of Vaccination against Covid-19 in Healthcare Professionals' (2021) Medicina Clinica 79, 82.
[377] Ahmed Bait Amer, 'Understanding the Ethical Theories in Medical Practice' (2019) 9 Open Journal of Nursing 188, 190-191.
[378] Refer to Beauchamp and Childress, *Principles of Biomedical Ethics*.
[379] J McCarthy, 'Principlism or Narrative Ethics: Must We Choose between Them?' (2003) 29 Medical Humanities 65, 66-67.
[380] Ibid 66.

### 4.3.1 History of Principlism

The Nuremberg war trials[381] in 1947 and the Declaration of Helsinki[382] highlighted the need to establish basic ethical principles when documents revealed inhumane medical experimentation by Nazi physicians who used concentration camp inmates as subjects. The Nuremberg Code was part of the decision in the Nuremberg trials of Nazi doctors after World War II. Despite containing ten universal moral conditions for a moral study, no basic moral principles were established.[383] Similarly, the World Medical Association issued the Declaration of Helsinki in 1964 which included practical rules for clinical research ethics but did not include universal moral concepts.[384]

Thereafter the Belmont Report and *Principles of Biomedical Ethics* were produced as the primary and early sources of principles of bioethics.[385] The Belmont Report by the National Commission for the Protection of Human Subjects advanced three principles: respect for persons, beneficence and justice.[386] The *Principles of Biomedical Ethics* presented basic principles suitable for application to ethical problems in medical practice.

### 4.3.2 Defining principlism

Beauchamp and Childress identified four main principles of medical ethics collectively known as principlism: autonomy, beneficence, non-maleficence and justice. These principles are considered as '*prima facie*' principles (i.e. non-absolute) which constitute the substantive

[381] Evelyn Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337 New England Journal of Medicine 1436, 1436.
[382] World Medical Association, 'World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects' 2013), accessed 9 February 2021, 2191-2194.
[383] Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code', 1437.
[384] World Medical Association, 'World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects' .
[385] Wamia Siddiqui and Richard R Sharp, 'Beyond the Belmont Report' (2021) 21 The American Journal of Bioethics .
[386] Ibid 3.

normative element for dealing with conflicts of biomedical ethics.[387] Principlism provides medical professionals with a guide to making bioethical decisions in everyday clinical practice. What is notable about them is that they are based on 'universal or objective nature'.[388] According to Beauchamp and Childress, 'the common morality contains moral norms that bind all persons in all places; no norms are more basic in the moral life'.[389] For example, a doctor can believe that providing a patient with information regarding their disease is morally obligatory because it follows the moral rule of telling the truth which is related to the principle of respecting patient autonomy.

*Prima facie* principles means that each principle is equally important unless they conflict with another principle when they should be weighed against each other to decide which should take precedence.[390] In a morally difficult situation and when there is a conflict between principles, principlism stipulates that none of the principles should have automatic privilege. A popular example is when dealing with Jehovah's Witnesses; the doctor must respect the patient's autonomy and wish to not receive blood products despite the overwhelming benefits of such treatment in saving the patient's life. To resolve the conflict, there are two specific processes, *specification* and *balancing* which may be applied, to which we will return later (see Section 4.4).

#### 4.3.2.1 Respect for autonomy

The word autonomy is derived from the Greek *autos* which means 'self' and *nomos* means 'rule or governance or law'.[391] As an adjective, 'autonomous' is a choice an individual makes

[387] Rauprich, 'Common Morality: Comment on Beauchamp and Childress', 44.
[388] McCarthy, 'Principlism or Narrative Ethics: Must We Choose between Them?', 66.
[389] Beauchamp and Childress, *Principles of Biomedical Ethics*, 13.
[390] Thomas R McCormick, 'Principle of Bioethics' (2018), accessed 5 February 2021.
[391] Beauchamp and Childress, *Principles of Biomedical Ethics*, 101.

and an 'autonomous person' is the agent who makes the choice or takes action.[392] The autonomous individual is expected to act freely which encompasses self-rule that is free from interference by others that limits individuals and prevents them from making meaningful choices.[393] Therefore, autonomy is an integral component of respect for people and their right to self-determination.[394] According to this principle, individuals have a moral obligation to respect individual self-determination so long as it does not infringe on the rights of others.

There are several versions of autonomy. Kant considered autonomy as a kind of self-control whereby individuals act autonomously as if according to a 'universal law'.[395] Beauchamp and Childress' description of autonomy is content neutral and does not require any reference to the content of their action or decision.[396] Their principle of autonomy focuses on the ability to make decisions. It states two conditions that are essential for autonomy: liberty, or independence from controlling influence, and agency, the capacity for intentional action. Factors and conditions to achieve autonomy must include intentionality, understanding and lack of controlling influences. These conditions can be applied to answer the research question.

Callahan, in '*Autonomy: A Moral Good, Not a Moral Obsession*', states what autonomy means in the healthcare setting:

> In the context of medicine, it is a value that has served to establish the rights of patients over physicians and the rights to be spared the paternalistic interventions of those who think they understand my welfare better than I do. The purpose of autonomy is to make me my own moral master.[397]

---

[392] *Autonomy in Moral and Political Philosophy* (2003).

[393] Gwandolen Reyes-IIllg, 'Respect for Patient Autonomy in Veterinary Medicine: A Relational Approach', Colorado State (2017).

[394] Sidney F Engelbrecht, 'Can Autonomy Be Limited- an Ethical and Legal Perspective in a South African Context' (2014) 32 Journal of Forensic Odonto-Somatology 34, 34.

[395] Wood, *Kantian Ethics*.

[396] Lisa Dive and Ainsley J. Newson, 'Reconceptualizing Autonomy for Bioethics' (2018) 28 Kennedy Institute of Ethics Journal 171, 171.

[397] Daniel Callahan, 'A Moral Good, Not a Moral Obsession' (1984) 14 The Hastings Center Report 40, 40.

Accordingly, patients have the right to accept or deny treatment as much as the right to access their own information.[398] There are however some restrictions on who is non-autonomous; for example, those who are mentally incompetent or who have lost the capacity to make autonomous decisions. Those who are mentally incompetent are said to fail to show that they are capable of understanding the nature, purpose and effects of life-saving treatment. Beauchamp and Childress stated that 'autonomous actions should not be subjected to controlling constraints by others unless the person is not competent'.[399] There are many facets that the principle of respect of autonomy can support: to tell the truth and not withhold information, to protect confidential information while respecting the privacy of others and to obtain informed consent from patients for shared decision-making. The essential obligation is to ensure that patients have the freedom to select and the ability to accept or reject information.[400]

Beauchamp and Childress' book states "the history of medical ethics the principles of non-maleficence and beneficence have both been invoked as the basis for paternalistic actions'.[401] In Chapter 5, I suggest that the principle to respect autonomy should be seen as a positive obligation that motivates actions including disclosing information to empower patients to be better informed and make the best decisions for themselves as 'their own moral master',[402] I elaborate on this further when I use this principle to justify wider access to enable and empower patients to make well-informed decisions.

---

398 *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290.

399 Beauchamp and Childress, *Principles of Biomedical Ethics*, 102.

400 Yusrita Zolkefli, 'Evaluating the Concept of Choice in Healthcare' (2017) 24 Malaysian Journal of Medical Sciences 92, 92.

401 Beauchamp and Childress, *Principles of Biomedical Ethics*, 216.

402 Callahan, 'A Moral Good, Not a Moral Obsession', 40.

#### 4.3.2.2 Beneficence and non-maleficence

Beneficence is a moral obligation to act for the benefit of others and non-maleficence is an obligation not to inflict harm on others.[403] In medical practice, Gillon emphasises the net benefit to patients; 'The obligation to provide a net benefit to patients also requires us to be clear about risk and probability when we make our assessments of harm and benefit'.[404] It is therefore essential to have empirical information on the probabilities of the various harms and benefits that may result from proposed healthcare interventions. For example, a mastectomy will constitute a net benefit to the woman if she has breast cancer, but in another aspect, it can also be seen as harmful to a woman's identity which cannot be outweighed even if the intention is to prolong life expectancy.[405]

It has been claimed that beneficence is optional, whereas non-maleficence is a mandatory obligation in which one must refrain from intentionally harming a person.[406] Beauchamp and Childress state that the principle of non-maleficence obligates us to refrain from causing harm to others.[407] Beneficence, or doing good, not only 'requires that we treat persons autonomously and refrain from harming them, but also that we contribute to their welfare'.[408] Therefore non-maleficence is a prohibition of action while beneficence carries a positive requirement for action which does not come with legal punishments if there is a failure to abide it. The beneficent actions express a commendable moral ideal, but they are not an obligation and the actor is not morally deficient if they fail to act beneficently.[409] Therefore, failing to act non-maleficently towards a party is *prima facie* immoral but failing to act beneficently toward a

403 Beauchamp and Childress, *Principles of Biomedical Ethics*, 202.
404 Gillon, 'Medical Ethics: Four Principles Plus Attention to Scope', 185.
405 Ibid 185.
406 *The Principle of Beneficence in Applied Ethics* (2008)
407 Beauchamp and Childress, *Principles of Biomedical Ethics*, 150.
408 Ibid 202.
409 Ibid 203.

party is not.[410] Using Covid-19 as an example, an individual who declines to have their Covid-19 vaccination fails to act beneficently but not necessarily immorally. However, if one had a Covid-19 infection and was aware of this and did not isolate but transmitted the virus to another person, they have failed to act non-maleficently, which can be considered immoral. As an individual in society, one is intrinsically obligated to refrain from intentionally harming another and yet not under any obligation to act good to benefit another. Other examples of the positive acts versus omissions in tort law include failing to rescue another person, which can be justifiable, but harm such as murder is not.[411] However, in healthcare, doctors do have a duty to act beneficently, as we shall see later.

This concept is inextricably linked to the theory of common morality which comprises a basic set of moral standards. For example, the act of non-maleficence is morally commendable in a society which is bound to norms that are morally constructed. Examples of these norms include not committing murder, not stealing and doing no harm to others. Other ethical theories are consistent with the principles of beneficence and non-maleficence. Utilitarianism, for example, emphasises the importance of consequences in which actions produce the most benefit.[412]

Harm itself is not well-defined in clinical practice. One might define 'harm' as a range of things which include every medical action including procedures or medical treatment with inherent complications and side effects. There are two types of harm described by Beauchamp and Childress: normative and non-normative.[413] Normative is a standard type of harm which is 'spontaneously' accepted by every moral person.[414] For example, a person breaking into a house is considered a wrongdoer which falls in the category of normative harm. Beauchamp

[410] Ibid 203.
[411] Theodore M Benditt, 'Liability for Failing to Rescue' (1982) 1 Law and Philosophy 391.
[412] *The History of Utilitarianism* (2009).
[413] Beauchamp and Childress, *Principles of Biomedical Ethics*.
[414] Bhaskarjit Neog, 'An Understanding of Common Morality', University Utrecht (2007) .

and Childress use non-normative harm in medical practice which is incurred without the notion of wrongdoing.[415] Examples range from the side effects of medications to informing a person of bad news. Harm can also be physical or non-physical suffering but in the medical context of principlism and for this thesis, anything which involves a setback to the patient's physical and psychological well-being is non-normative harm.

#### 4.3.2.3 Justice

Beauchamp and Childress use the principle of justice to address the issue of fairness in medical practice as healthcare resources are not infinite and are influenced by capacity and funding. For example, during the Covid-19 pandemic, intensivists applied this principle to decide which patients were candidates for the intensive care unit (ICU) based on the likely outcome. Beauchamp and Childress state that there is no one-size-fits-all theory of justice that can answer all the questions and problems in modern medicine. Thus, they divide justice into two different aspects: a formal principle and a material principle. [416]

The formal principle states that everyone must receive equal treatment. This can be traced back to Aristotelean ethics.[417] It is called 'formal' as no characteristics make a person equal and no manner was identified as equals are treated equally.[418] For example, a 50-year-old independent man with a new diagnosis of lung cancer is not the same as an 85-year-old frail man with the same diagnosis and equal treatment options are not viable as chemotherapy is likely to cause more harm than benefit to a frail elderly person. The material principle specifies the characteristics for equal treatment, which 'identify the substantive properties for distribution'.[419] The term 'distribution of justice' refers to how society's rights and obligations,

[415] Beauchamp and Childress, *Principles of Biomedical Ethics*, 153.
[416] Ibid 250.
[417] Louis Pojman, 'Theories of Equality: A Critical Analysis' (1995) 23 Behaviour and Philosophy 1.
[418] Beauchamp and Childress, *Principles of Biomedical Ethics*, 250.
[419] Ibid 251.

including civil and political rights, are distributed.[420] There are different principles of distributive justice: '1) an equal share 2) according to need 3) according to effort 4) according to contribution 5) according to merit and 6) according to free-market exchanges'.[421] Another example from the Covid-19 pandemic includes one ICU bed being available for two patients with Covid-19-related respiratory failure as the doctors decide which patient is likely to benefit most and have a favourable and acceptable outcome from admission to ICU; the 70- year old male with no advanced comorbidities or a 65-year old male who is already on long-term oxygen due to advanced chronic respiratory disease.

Fair opportunity is the idea that:

> No person should receive social benefits on the basis of undeserved advantageous properties and that no persons should be denied social benefits on the basis of undeserved disadvantageous properties. [422]

For example, needing long-term oxygen due to having a chronic terminal lung condition is not a direct responsibility of an individual.

Although Beauchamp and Childress support the notion of fair opportunity, these properties should not be the basis for determining the allocation of benefits and risks because there is no fair opportunity to obtain them.[423] In this analogy, they use the example of people with functional disabilities who lack capacity and need healthcare to improve their condition. According to Beauchamp and Childress, if such people are responsible for their health they might be entitled to healthcare services but if they are not, the fair rule of opportunity demands they receive help to ameliorate their circumstances.[424]

---

[420] Ibid 251.
[421] Basil Varkey, 'Principles of Clinical Ethics and Their Application to Practice' (2021) 30 Medical Principles and Practice 17, 21.
[422] Beauchamp and Childress, *Principles of Biomedical Ethics*, 263.
[423] Ibid 263.
[424] Ibid 263.

For this thesis, the definition of justice is based on Beauchamp and Childress's elaboration.

As discussed, justice within principlism highlights the delivery of equitable healthcare services and resources at an individual level. The term 'justice' in Beauchamp and Childress refers to 'fair, equitable and appropriate distribution' in society.[425] In other words, providing an equal share of limited resources to every individual seeking medical care defines justice regardless of the socioeconomic states. While medical records should be fairly accessible to all individuals despite their education and socioeconomic background, the thesis uses the balancing act to justify widening access from the doctor's and patient's perspectives. Therefore, justice in the form of fairness and equitable access in this matter can be justified when widening access in Malaysia exists. Also, a patient's determination of rights and justice to access does not apply directly to address automatic granting if the process is not endorsed amongst the stakeholders, i.e. doctors and lawmakers. Pursuing justice, which involves creating an equitable society whereby the rights of all individuals should be recognised and protected, should not be undermined. Nonetheless for the sake of answering Part Two in this ethical analysis, I have not included justice. Justice is excluded from this equation, as striking the right balance for and against widening patient access should be in the narrative of patient autonomy, benefits and harm, within which such agreement is then fairly impacted on patients.

Thus, justice is the least relevant principle in the framework of widening access to medical records and will not be discussed although the concept of justice in medical practice extends to the rights of individuals and of society.

[425] Beauchamp and Childress, *Principles of Biomedical Ethics*, 226.

### 4.4 Resolution of conflict

In the earlier example of the Jehovah's witness, to support the practice of these principles, Shea claimed two processes for this bioethical theory to take effect: specification, which involves adding content to general moral principles, and balancing which is the process of judging the relative weight of conflicting principles.[426] Beauchamp and Childress admit that in making balancing judgements, 'some intuitive and subjective weightings are unavoidable, just as they are everywhere in life when we must balance competing goods'.[427] At the same time, they insist that 'balancing [...] is a process of finding reasons to support belief about which normal norms should prevail'.[428] Beauchamp and Childress adopted John Rawl's reflective equilibrium, claiming that it 'occurs when we evaluate the strengths and weaknesses of all plausible moral judgements, principles and relevant background theories'.[429] In essence, they amalgamate the reflective equilibrium with commonly accepted moral justification.

#### 4.4.1 Specification

Principlism holds that its principles must be specified to give guidance for actions in healthcare and medical research.[430] How to obtain informed consent, how much information needs to be disclosed and how to maintain confidentiality are some examples. Specification renders principles useful by making them relevant. With principlism, it allows justification for widening patient access to medical records. By adding context-specific and action-guiding substance to basic moral norms, the specification can be used to apply them to specific

[426] Matthew Shea, 'Principlism's Balancing Act: Why the Principles of Biomedical Ethics Need a Theory of the Good' (2020) 45 Journal of Medicine and Philosophy 441, 444.
[427] Beauchamp and Childress, *Principles of Biomedical Ethics*, 20.
[428] Ibid 20.
[429] *Principlism*.
[430] Ibid.

circumstances and issues.[431] Richardson[432] offered a definition of specification which Beauchamp and Childress have adopted: 'spelling out where, when, why, how, by what means, to whom, or by whom the action is done or avoided'.[433] 'Specification entails that every instance of a particular norm is also an instance of the general norm'.[434] Technically, the specification requires two norms, one specified and one less specific, and two conditions.[435] For example, providing patient access to medical records (a specified norm) is an instance of respecting the patient's autonomy (a general norm). Obtaining informed consent is also an instance of respecting patient autonomy.[436] Thus, a 'string of progressive specifications is necessary to establish a transparent connection between basic norm and a particular moral issue'.[437] Although the defined norm has different content to the less specific norm from which it is generated, it represents the less specific normative commitment. Hence, 'the moral authority of the basic norm is transmitted step by step all along the way to the final, specific judgement'.[438]

This is why I will use principlism as my main framework to justify widening patient access. As the method of specification requires the exercise of moral deliberation and usually more than one line of specification of principles is commonly available when confronting practical problems and disagreements, I aim to introduce the specified norms through concepts that

---

431 Ibid.

432 Henry S Richardson, 'Specifying Norms as a Way to Resolve Concrete Ethical Problems' (1990) 19 Philosophy and Public Affairs 279.

433 Richardson, 'Specifying, Balancing, and Interpreting Bioethical Principles', 289.

434 *Principlism*, 2286.

435 Richardson, 'Specifying Norms as a Way to Resolve Concrete Ethical Problems', 297-299. Carson Strong, 'Specified Principlism: What Is It, and Does It Really Resolve Cases Better Than Casuistry?' (2000) 25 Journal of Medicine and Philosophy .

436 *Principlism*, 2286.

437 Ibid 2286.

438 Ibid 2286.

might be encountered in the healthcare setting and use specification to ethically justify the need to widen patient access.

### 4.4.2 Balancing

The theory of *prima facie* obligations was created by Ross, an Oxford philosopher. He distinguished between seeming and actual obligations. Actual obligations are governed by the moral codes of society. For example, performing a duty is morally right whereas failing to act is morally wrong. An act of *prima facie* duty is when there is a moral reason in favour of doing the act but one that can be outweighed by other moral reasons. Unless it clashes with another commitment that is more important in the context, an obligation must be fulfilled.[439]

In principlism, moral problems may arise as conflicts of *prima facie* exist. These concepts are bound closely together and connected to why widening patient access should be ethically justified. Where conflicts between these duties cannot be resolved, balancing them may resolve conflict. For example, issues involving potential conflicts between respect of autonomy (refusal of blood products) and duties of beneficence (blood products would benefit the patient) and non-maleficence (blood products would prevent the harm associated with not having them). However, rather than giving reasons for justifying balancing principles to make judgements, Beauchamp and Childress just asserted their value.[440] They do not recognise '*a priori* ranking among these opposing obligations, and so the proper balance will depend on the circumstances, rather than be determined by any general rule'.[441] An example was given by Beauchamp and Childress in their book: that of a patient who does not want to know the results of his HIV test, although the doctor knows that the test is positive.[442] The patient has the right

[439] David Ross and Philip Stratton-Lake, *The Right and the Good* (Oxford University Press 2002), 156.
[440] Tom Tomlinson, 'Balancing Principles in Beauchamp and Childress' <https://www.bu.edu/wcp/Papers/Bioe/BioeToml.htm>, accessed 6 March 2020.
[441] Ibid.
[442] Beauchamp and Childress, *Principles of Biomedical Ethics*

to choose what information they want to receive, but their wilful ignorance may put their sexual partners at risk and the physician's duty of non-maleficence would be violated if they ignored such risks to others. Which responsibility is more important and why?[443] Beauchamp and Childress answer in one sentence:

> In light of the possible consequences, the disclosure was justified although the patient did not want the information.[444]

This conclusion is not supported by any evidence. It is simply the result of a moral intuition which was not supported by any reasoning.[445]

Principlism is a valuable framework as it resolves moral issues by balancing judgements and through specification. Balancing would answer questions with reasons and justification. It answers the question by the assertion of what is taken to be obvious to moral common sense.[446] Balancing judgements are also the 'results of the careful reasoning that involves evaluation of evidence, assessment of consequences, a search for alternatives and consideration of possible biases and partialities, and other heuristic measures'.[447] Thus, principlism allows not one definite ethical solution, but 'many plurality of acceptable solutions'.[448] As this thesis does not seek to criticise principlism theory, but rather to use its strength to support its efforts to answer the research question, the evaluation of the contrary will not be my main focus in the next chapter although critiques should be acknowledged. [449]

---

[443] Ibid 21.
[444] Ibid 20.
[445] Tomlinson, 'Balancing Principles in Beauchamp and Childress'.
[446] Ibid.
[447] Ibid; *Principlism*, 2287.
[448] *Principlism*, 2287.
[449] Tom Walker, 'What Principlism Misses' (2009) 35 Journal of Medical Ethics 229.

## 4.5 Conclusion

This chapter introduced the main ethical theories offered for medical practice including the deontological, utilitarian and principlism. While the discussion on the strength and weaknesses of these theories are not the main focus of this thesis, this chapter forms a basis of the approach to answer my research question using an ethical lens. Gillon stated:

> [Principlism] is a framework that is compatible with other universalisable ethical approaches, including deontological, utilitarian and virtues approaches and several others. Most importantly, it provides a universalisable set of *prima facie* moral commitments to which all doctors can subscribe, whatever their culture, religion (or lack of religion), philosophy or life stance; in addition, it provides a basic moral language and a basic moral analytic framework that all interested in biomedical ethics can share.[450]

In summary, the principlism approach argues that the principles of autonomy, beneficence, non-maleficence and justice express the general values underlying rules in common morality, which is defined as 'the set of norms that all morally serious persons share'.[451] According to Gillon, it provides a framework for healthcare professionals and the four principles can justify 'all the substantive and universalisable moral claims in medical ethics'.[452] The four principles almost consistently address dilemmas in clinical decision-making to ensure that all aspects of meaningful outcomes such as better health, risk reduction, patient autonomy, privacy, fairness and appropriateness are considered. Therefore, principlism will be mainly utilised to argue for and against patient access to medical records in the next two chapters.

---

[450] Raanan Gillon, 'Defending the Four Principles Approach as a Good Basis for Good Medical Practice and Therefore for Good Medical Ethics' (2015) 41 Journal of Medical Ethics 111,115.

[451] Walker, 'What Principlism Misses', 229.

[452] Raanan Gillon, 'Ethics Needs Principles—Four Can Encompass the Rest—and Respect for Autonomy Should Be "First among Equals"' (2003) 29 Journal of Medical Ethics 307, 308.

# Chapter 5. The application of principlism to information transmission in the doctor-patient relationship

## 5.1 Introduction

In the last chapter, I discussed the ethical theories and focused on the theory of principlism in medical practice. In this chapter, I will discuss the application of principlism to information transmission, which aims to provide a thrust to the overall argument. Due to the conflicting values of different ethical principles which reflect the competing interests inherent in the doctor-patient relationship, this is an important part of the framework in which to discuss applied ethics. This chapter does not attempt to rigorously examine all ethical theories but provides sufficient background on how they can be applied to aspects of information transmission in the doctor-patient relationship before moving on to patient access to medical records in which these applications are adapted to justify wider access. I will illustrate that medical records are a medium of information transmission, which will act as the main reason for widening access in this thesis. This chapter aims to adopt a theoretical perspective on how one type of information transmission (for example, providing an informed consent) can be used as a justification to employ another method of information transmission, to strengthen the argument for widening patient access to their medical records using the framework of principlism.

Beauchamp and Childress state that limiting patient choice and autonomy is a tension between the obligation of care that healthcare professionals hold[453] and competing interests struggle amongst themselves to achieve a logical conclusion. Barsky defined ethical conflicts as a 'crisis in interaction in which each party becomes wrapped in self-interest, fails to see the other side's

[453] Beauchamp and Childress, *Principles of Biomedical Ethics*

arguments and feels victimised, hurt, or disempowered'.[454] Edelstein stated that conflict emerges 'when patients, surrogates or clinicians perceive that their goals related to care and outcomes are being thwarted by the incompatible goal of others'.[455] Ethical conflicts for which solutions are not well-established in clinical treatment are also on the rise for a variety of reasons, including longer life expectancy, more sophisticated technology, higher public expectations on health outcomes, increased emphasis on patients' rights, greater cultural and religious diversity as well as limited resources.[456] To ensure morally justified decisions, clinicians are supposed to employ ethical theories and frameworks.[457] Principlism is widely regarded as a basic paradigm for considering ethical concerns with complex ethical difficulties as one or more of the four principles may clash.[458]

Kasule concludes that there are no fully adequate ethical theories that can address all ethical or moral dilemmas in a doctor-patient relationship.[459] None of the theories mentioned above has all the attributes of a good ethical theory: 'clear, coherent, practicable and absolute'.[460] It is practical to use more than one theory to solve a specific ethical question in clinical practice. While the strength of principlism is clarity, simplicity, and universality, it neglects the emotional and human factors that influence complex decision-making. A claim of universality is also a stretch as each doctor-patient relationship and the physical and emotive environment in which these are conducted are unique.

---

454 Allan Barsky, 'A Conflict Resolution Approach to Teaching Ethical Decision Making: Bridging Conflicting Values.' (2008) 83 Journal of Jewish Communal Service 164, 166.

455 LM Edelstein and others, 'Communication and Conflict Management Training for Clinical Bioethics Committee' (2009) HEC Forum , 342.

456 Carol Pavlish and others, 'The Nature of Ethical Conflicts and the Meaning of Moral Community in Oncology Practice' (2014) 41 Oncology Nursing Forum .

457 Jacqualine Lindrige, 'Principlism: When Values Conflict' (2017) 9 Journal of Paramedic Practice 1,1.

458 Ibid 2.

459 Omar Hasan Kasule, 'Medical Ethics from Maqasid Al Shari'at' (2005), accessed September 10 2020.

460 Ibid.

I intend to apply principlism, particularly in the respect for autonomy, beneficence and non-maleficence as a framework for the doctor-patient relationship. These are then used to establish inherent competing arguments that are linked to either widening or restricting access to medical records. The ethical conflicts I am engaging in are underpinned by different and often opposing sets of values and beliefs and how principlism assists in helping to resolve these conflicts. In the next section, I provide ways of approaching these ethical conflicts that may be encountered during doctor and patient information transmission and determine whether widening patient access as part of transmitting information is ethically justifiable.

## 5.2 The discussion of ethical principles on information transmission in a doctor-patient relationship

Communication of information on medical care and the dynamics of information transmission are particularly important as they are closely related to outcomes in healthcare.[461] These characteristics which emerge in the doctor-patient relationship can be extended as an analogy in different types of information transmission which encapsulate the principles of medical ethics. This chapter aims to adopt a theoretical perspective on how one type of information transmission can be used as a justification to employ another kind of information transmission which may strengthen the justifications for widening patient access by examining the similarities of both characteristics that they possessed by using the framework of principlism.

[461] Howard Waitzkin and others, 'The Informative Process in Medical Care: A Preliminary Report with Implications for Instructional Communication' (1978) 7 Instructional Science 385, 385.

### 5.2.1 Respect for autonomy

Respect for autonomy means autonomy is an integral component of respect for individuals and their right to self-determination.[462] The concept of informed consent probably best encapsulates the essence of respect for autonomy. In this section, I will unpack the intricacies that underlie informed consent and its relation to autonomy. The concept of informed consent is important as justifying wider access for patients to their medical records falls under the same motivation: respect for autonomy.

#### 5.2.1.1 Informed consent – the legal and ethical necessity for duty of care and respect for autonomy

The ethical arguments for informed consent and have changed the practice of clinical decision-making in areas such as the duty of care, the duty to advise and how doctors provide comprehensible information. Information in informed consent is transmitted by the doctor within the doctor-patient relationship, whereas patient access to medical records is transmitted by an administrative mechanism in which doctors or hospital providers provide the records.

Consent in medical practice refers to a patient's voluntary authorisation to agree or refuse medical intervention.[463] Usually, the legal and ethical requirements of consent for clinical practice are provided by the national medical regulators through the code of ethics and clinical practice guidelines and case laws in that country.[464] Patients have the right to know of the risks and benefits of a procedure or medical intervention and any alternative treatment under human rights treaties and the common law.

---

462 Engelbrecht, 'Can Autonomy Be Limited- an Ethical and Legal Perspective in a South African Context', 34.

463 Parth Shah and others, *Informed Consent* (StatPearls Publishing 2021) .

464 General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008); Malaysia Medical Council, *Consent for Treatment of Patients by Registered Medical Practitioner* (2017) .

The development of informed consent can be traced back to the 19th century and serves as a fundamental argument for preserving patient autonomy.[465] Dworkin claims that 'all discussions of the nature of informed consent and its rationale refer to patient autonomy'.[466] A more recent opinion by Manson and O'Neill is that 'the reason most commonly given for the expansion, entrenchment and elaboration of informed consent requirements is that they are needed to secure respect for individual autonomy'.[467] In Malaysia, the MMC Guidelines state that informed consent is 'the voluntary acquiescence by a person to the proposal of another; the act or result of reaching an accord'.[468] In the UK, NHS Consent or Examination for Treatment states:[469]

> The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing).[470]

There are three major elements of valid consent for medical treatment: adequate information transmission, comprehensible information and voluntariness.[471] I will unpack the different aspects of the first element later, but for voluntariness, it means that the decision to consent is not due to coercion or pressure.

An argument against widening patient access is the element of comprehensible information. Medical records are not created for the patients in the first place. Medical jargon and clinical communications may be incomprehensible and cause confusion or anxiety for patients. The

---

465 Ruth R. Faden and Tom L Beauchamp, *A History and Theory of Informed Consent* (Oxford University Press 1986).
466 Gerald Dworkin, 'The Nature of Autonomy', (Cambridge University Press 1988), 5.
467 Neil C Manson and Onora O'Neil, *Rethinking Informed Consent in Bioethics* (Cambridge University Press 2007), 185.
468 Malaysia Medical Council, *Consent for Treatment of Patients by Registered Medical Practitioner*, cl 1.
469 NHS Foundation Trust, *Consent to Examination or Treatment Policy* (2019).
470 Ibid.
471 Jahn Kassim, *Law and Ethics Relating to Medical Profession*.

element of comprehensible information has the following elements: (1) **understanding** of treatment-related information, with an emphasis on the types of information that must be disclosed under the law of informed consent; (2) **appreciation** of the importance of knowledge in the patient's case, with an emphasis on the nature of the condition and whether or not treatment will be beneficial; 3) **reasoning** in focusing on the ability to compare alternatives in light of their effects, including the ability to draw inferences about the effect of the alternatives on the patient's daily life during the treatment decision-making process; and (4) **expressing** a choice about treatment.[472] Unlike an in-person clinic consultation where there are two ways of communication between patient and doctor, it can be argued that patients reading medical records directly do not address these four elements intrinsically due to the primary function of the records as a tool designed for medical professionals.

Informed consent is based on a fundamental justification: respect for patient autonomy. This means that despite understanding, appreciation, reasoning and expressing a choice of treatment, patients apply the information and make clinical decisions in line with their personal beliefs and values. It is the essence of self-determination that is unique in every individual's experience that protects the right to autonomy, decision-making capabilities and sanctity of life.[473] It is an ethical necessity which places a greater ethical value on respecting patient autonomy, and a legal necessity that protects the patient's best interest by legally upholding respect for patient autonomy. This conceptualisation of informed consent makes it appealing as the result of medical ethics (i.e., right for autonomy) and a framework of law and medical practice that serves as a legal theory.[474] Informed consent is a legal necessity because it is also

[472] Paul S Appelbaum, 'Assessing of Patients' Competence to Consent to Treatment' (2007) 357 The New England Journal of Medicine 1834, 1836.
[473] Daniel E Hall, Allan V Prochazka and Aaron S Fink, 'Informed Consent for Clinical Treatment' (2012) 184 Canadian Medical Association Journal 533, 533.
[474] KH Satyanarayana Rao, *Informed Consent: An Ethical Obligation or Legal Compulsion* (Journal of Cutaneis Aesthetic Surgery, (2008), 33.

a moral necessity and ethically important.[475] It is this blended argument that I propose later to support wider access to medical records; patients should be able to access their medical records, not only out of respect for their autonomy, but with the support of a legal stamp such as practised for informed consent.

#### 5.2.1.1.1 Duty to advise

Once a relationship is established between a doctor and a patient, the doctor owes the patient a duty of care. Where a doctor's practice has failed to meet an appropriate standard, there is a potential breach of professional duty.[476] One of these duties is the duty to advise in which a doctor must provide relevant information to the patient about a condition they are suffering from, including the nature of the condition, the options for treatment and the benefit and risks of treatment or non-treatment. It is a fundamental aim of the informed consent doctrine to protect the patient's autonomy. Hence, informed consent is a legal doctrine that underpins this important right that requires doctors to perform their duty to advise.

Medical negligence cases involving informed consent established an authoritative standard in the duty to advise.[477] The development of the law of informed consent in Malaysia has shown a shift in the matter of a doctor's obligation to inform about risk. Before *Foo Fio Na v Hospital Assunta & Anor,*[478] the Court of Appeal was more inclined to follow the doctor-oriented approach adopted by the UK House of Lords in *Sidaway v Board of Governors of the Bethlem Royal and Maudsley Hospital*[479] which concerned the duty of a surgeon to inform a patient of the risks before undergoing an operation. Although there was no evidence that the operation

---

[475] Elizabeth Ngo and others, 'The Importance of the Medical Record: A Critical Professional Responsibility' (2016) 31 Medical Practice Management 305, 306.
[476] Refer to Puteri Nemie Jahn Kassim, *Medical Negligence in Malaysia: Cases and Commentary* (Sweet and Maxwell Asia 2009).
[477] Refer to *Foo Fio Na v Hospital Assunta & Anor* ; Shah and others, *Informed Consent*.
[478] Refer to *Foo Fio Na v Hospital Assunta & Anor* ; *Dr Soo Fook Mun v Foo Fio Na & Anor and Another Appeal* [2001] 2 CLJ 45.
[479] Refer to *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.

had been carried out negligently, the plaintiff argued that the defendant had been negligent in not telling her the risk of damage to the spinal cord. In the *Foo Fio Na* case, the Court held that it was the matter for the doctor's clinical judgement as to which risks should be disclosed to allow the patient to make a rational decision. This approach addressed the question of how much information is considered professionally appropriate to give to the patient and whether a doctor is not negligent as long as a responsible body of medical practitioners considers their conduct as logical or reasonable.[480] In *Foo Fio Na,* the Federal Court held that the doctor was negligent in failing to inform the patient of the risk. The Court viewed the *Bolam* approach as being 'overprotective and deferential' to the medical profession[481]. It is the court that determines the doctors' conduct and not the profession. The Federal Court held that 'the *Rogers v Whitaker* test would be a more appropriate and a viable test of this millennium'.[482] The *Bolam* test means that a doctor is not negligent if they have acted in accordance with practice accepted as proper by a responsible body of men skilled in that particular art.[483] The *Roger* test is the duty to warn patients of material risks. [484]

Although *Foo Fio Na* was resolved at a higher level, the initial Malaysian High Courts adopted the doctor-oriented *Bolam* approach in a number of cases including *Hassan Datolah v Government of Malaysia*[485] until the patient was granted leave to appeal by the Federal Court. However, in delivering its final judgment in *Foo Fio Na*, the Federal Court ruled that 'the

---

480 *Bolitho v City of Hackney Health Authority* [1998] AC 232 .

481 *Foo Fio Na v Hospital Assunta & Anor* [26].

482 Ibid [611].

483 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

484 *Rogers v Whitaker* [1992] 175 CLR 479 *Bolam v Friern Hospital Management Committee*. In this case, patient had sympathetic ophthalmia in her left eye as a result of an unsuccessful operation on her right eye, which led to her becoming essentially blind. There is no doubt that the surgery was carried out with the necessary skill and care, but Ms. Whitaker asked the court for relief because the ophthalmologist, Dr. Christopher Rogers, neglected to inform her of the possibility (roughly 1 in 14,000) that the sympathetic ophthalmia condition could manifest. Despite Ms. Whitaker's expressed explicit concern that her "good eye" not be injured, the trial court's award of damages was upheld because Dr. Rogers failed to warn her of any possible dangers involved with the procedure.

485 Refer to *Hassan Datolah v Government of Malaysia* [2003] 5 CLJ 355.

*Bolam* test has no relevance to the duty and standard of care of a medical practitioner in providing advice to a patient on the inherent and material risks of the proposed treatment'.[486] This ruling by the highest court in the land put some finality on how Malaysian courts would now address information disclosure[487] which is now a legal requirement and a standard duty of care to patients in providing advice not limited to the *Bolam* concept in which the doctor decides on the relevance of the information provided.

Another key UK precedent is *Montgomery*[488] which saw an evolutionary change from *Bolam* to *Montgomery* in medical practice in respect of information transmission.[489] The *Montgomery* test overturned the decision in *Sidaway* in which the validity of consent was until 2015 based on whether a reasonable body of medical opinion would agree. As the pregnant mother was a diabetic patient who had the potential of delivering a large baby, the obstetrician failed to provide an alternative of a caesarean delivery due to the risk of shoulder dystocia if the baby was born through a vaginal delivery. The risk of shoulder dystocia was not disclosed despite the material risks developing of 9-10%. The Supreme Court held that the extent of information given to the patient about the risks of the proposed treatment is not to be determined by the skilled doctor, but by a reasonable one in the context of a reasonable patient understanding the risks during the process of a health decision.[490] The doctor must recognise the patient's legal and ethical rights to autonomy and informed choice. Once the patient has been fully informed about the risks, they can choose to pursue treatment, alternative options, or no treatment at all: 'patients are now

[486] *Foo Fio Na v Hospital Assunta & Anor* [36].
[487] Matthew Thomas, '*Rogers v Whitaker* Lands on Malaysian Shores - Is There Now a Patient's Right to Know in Malaysia' (2009) Singapore Journal of Legal Studies 182, 191.
[488] Refer to *Montgomery v Lanarkshire Health Board* [61].
[489] Albert Lee, ''*Bolam'* to '*Montgomery'* Is Result of Evolutionary Change of Medical Practice Towards Patient-Centred Care' (2017) 93 Postgraduate Medical Journal 46.
[490] *Montgomery v Lanarkshire Health Board* [87].

widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession'.[491]

Interestingly, the GMC played a role in the Supreme Court's judgment in which the Court referred to the GMC's Guidance of Good Medical Practice, which states the duties of the doctors registered in the GMC:

> Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.[492]

Another guidance by the GMC on Consent: Patients and Doctors Making Decisions Together describes a basic model partnership between doctors and patients.

> The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice.[493]

The GMC, which intervened to make submissions in the *Montgomery* case, claimed that the decision had enabled the UK law to align with current GMC guidance. Based on this case, *Montgomery* changed the law on the impact of doctor's duties in the GMC from a mere guidance into a legal requirement.[494]

While the court case merely reflected good practice as already specified by the GMC, the case also generated further improvement of the GMC when it issued its guidance of professional

---

[491] Ibid

[492] General Medical Council, 'Good Medical Practice - Ethical Guidance', para 77.

[493] General Medical Council, *Consent: Patients and Doctors Making Decisions Together*, para 5.

[494] Isabelle Le Gallez and others, '*Montgomery's* Legal and Practical Impact: A Systematic Review at 6 Years' (2022) 28 Journal of Evaluation in Clinical Practice 690 , 695.

standards and ethics for doctors in decision making and consent effective from 9 November 2020. The theme of the guidance includes seven principles:

1) All patients have the right to be involved in the decisions about their treatment and care to be supported to make decisions if able;
2) Decision making is an ongoing process focused on meaningful dialogue; the exchange of relevant information specific to the individual patient;
3) All patients have the right to be listened to, and given the information they need to make a decision and the time and support that they need to understand it;
4) Doctors must try and find out what matters to patients so they can share relevant information about the benefits and harms of proposed actions and reasonable alternatives, including the option to take no action;
5) Doctors must start from the presumption that all adult patients have the capacity to make decisions about their treatment and care;
6) The choice of treatment or care for patients who lack capacity must be of overall benefit to them and the decisions should be made in consultation with those who are close to them or advocating for them and
7) Patients whose right to consent is affected by law should be supported to be involved in the decision- making process, and to exercise choice if possible.[495]

This case highlighted that obtaining informed consent is a process and the outcome of this process is not just to secure an agreement with a signature on the consent form. [496] The courts have also highlighted the requirement for patients' full understanding of the proposed medical intervention before making an informed decision. [497] In relation to the risks, physicians are also advised to warn patients if treatment may cause a serious adverse outcome, in order to obtain full and informed consent before they undergo medical treatment. The doctor must disclose risks that a reasonable person in the patient's position would attach significance to and risks that the doctor should reasonably be aware that the actual patient would attach significance to.[498]

[495] General Medical Council, *Decision Making and Consent* (2020) .
[496] General Medical Council, *Consent: Patients and Doctors Making Decisions Together*
[497] *Montgomery v Lanarkshire Health Board* [81]; *Gurmit Kaur a/P Jaswant Singh v Tung Shin Hospital & Anor* [2012] MLJ 260.
[498] *Montgomery v Lanarkshire Health Board* [87] .

As informed consent is defined as what a reasonable patient would wish to know, [499] one way is to discern information needed by the patient through access to comprehensible information during the process. The Court did give the caveat known as the 'therapeutic exception' which allows a doctor to withhold information from the patient if the doctor is convinced that disclosing it would put the patient's health at risk. The Court however emphasised that this is a very limited exception and did not apply in *Montgomery*. There is a downside to this approach as *Montgomery* could lead to more defensive practice in which all information, including risks deemed negligible, is provided as predicting what a 'reasonable' patient would want to know is challenging.

Interestingly, as portrayed in *Montgomery*, the GMC as the regulator has a footing in influencing the Courts' decisions, as the GMC's guidance has been in place for some time. While *Montgomery* changed the legal position of the GMC guidance, it illustrates how the GMC can influence the Court's decision on issues like informed consent and how decision-making and consent are linked to the doctor's role in offering advice and keeping patients fully informed. However, the term defined as 'material risks' was only established thereafter in the GMC. The case illustrated two key concepts, namely the importance of patient autonomy and the test for the materiality of risk, which only became more evident in the current guidelines. 'A reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'[500] and therefore it should be construed that informed consent must be

[499] John T James, Darwin Jay Eakins and Robert R Scully, 'Informed Consent, Shared-Decision Making and a Reasonable Patient's Wishes Based on a Cross-Sectional, National Survey in the USA Using a Hypothetical Scenario' (2019) 9 BMJ Open 1, 2,4.

[500] *Montgomery v Lanarkshire Health Board* [87]; *Rogers v Whitaker* [1992] 175 CLR 479, 490.

fully informed and that the doctor is required to act reasonably to ensure that the material risks and alternative treatments have been explained.[501]

The *Montgomery* case may be applicable in Malaysia's existing legal framework using the MMC's Guidelines for Consent, which specify what information should be disclosed. It is yet to be determined whether Malaysia will have the opportunity to legalise guidance from a regulator such as the MMC. Expectations provided by judicial judgments in Malaysia using the MMC's guidance have never been put into practice and this includes patients' right to access their medical records in Malaysia[502].

In short, *Montgomery* has changed legally how the UK practises informed consent and has fostered a more patient-centred care and enhanced autonomy. *Montgomery* illustrated that the guidance from the GMC can influence a doctor's practice as a legal requirement and liability, while this application remains unfolding in Malaysia.[503]

#### 5.2.1.1.2 Doctors as providers for information transmission

Although ensuring adequate information transmission is part of the elements of valid consent, it is also a part of respect for autonomy. To make an autonomous decision, the patient must have adequate information, meaning all the necessary information to make the decision, hence simultaneously putting the validity to the consent. This overlap shows the importance and role of ensuring adequate information in information transmission.

Several cases in Malaysia have highlighted the inadequacy of healthcare providers in providing adequate information to patients and their lack of understanding of the treatment they received

---

[501] Ibid.

[502] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors* ; *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*.

[503] Le Gallez and others, '*Montgomery's* Legal and Practical Impact: A Systematic Review at 6 Years', 698.

or the procedure performed.[504] The informed consent standard stipulated by the Malaysian courts focuses on the information of the proposed intervention including diagnosis, benefit, alternatives and disclosure.[505] Valid consent is incorporated into practice by assigning the doctor as an information provider to uphold the patient's autonomy to independently make decisions based on disclosed information.[506] One of the elements of valid consent is that the doctor respects the patient's right to self-determination and allows them to voluntarily make their healthcare decisions without coercion or outside influence. However, the doctor's competing interest to ensure the quality of care might not reflect a patient's preference and the information provided is usually selective.[507] For example, a doctor may feel that listing less successful options to treat cancer is time-consuming and may confuse the patient. One research study was performed on a group of nephrologists which revealed that doctors use information to influence a patient's decision on treatment. 'You can always present information so they select the treatment you want them to'.[508] Therefore, the doctor as provider of communication remains a core element in a clinical decision, as information needs to be comprehensible for the informed consent to be valid.

There are different types of communication in the doctor-patient relationship including verbal and non-verbal. Effective communication relies on many factors including the patient's beliefs, values and level of education.[509] Hence, doctors must adapt their communication strategies to the individual patient by exploring the patient's attitude and preference for their health. Some

---

[504] Refer to *Abdul Razak Bin Datuk Abu Samah v Raja Badrul Hisham Bin Raja Zezeman Shah and Ors* [2013] MLJ 34; *Norizan Bte Abd Rahman v Dr Arthur Samuel* [2013] MLJ 385.

[505] Hall, Prochazka and Fink, 'Informed Consent for Clinical Treatment', 534.

[506] Karen L McLean and Sharon E Card, 'Informed Consent Skills in Internal Medicine Residency: How Are Residents Taught, and What Do They Learn' (2004) 79 Academic Medicine 128.

[507] Rebecca E Say and Richard Thomson, 'The Importance of Patient Preferences in Treatment Decisions—Challenges for Doctors' (2003) 327 BMJ 542

[508] Ibid 543.

[509] Anthony C Berman and Darryl S Chutka, 'Assessing Effective Physician-Patient Communication Skills: "Are You Listening to Me, Doc?"' (2016) 28 Korean Journal of Medical Education 243, 243.

would prefer to have as much information as possible, while others would rather be passive or less active recipients of information from their doctors, trusting that their doctors will only provide information deemed relevant and required. Although verbal consultation is still the norm in clinic consultations, information comes in a variety of forms and some patients prefer information that is visible and documented. Access to medical records in real-time or a documented summary of a consultation can help patients process the information outside the clinic space without the pressure of a healthcare professional being in the same room.

There are differences in how these forms of transmission are configured in informed consent and access to medical records. Providing information that addresses the patient's information needs, choices, beliefs and goals, safety and autonomy are the foundation of delivering information to a 'reasonable patient' standard.[510] However, one can argue that maintaining autonomy in a reasonable patient standard is a two-way street requiring both patient's and doctor's responsibility in ensuring that the amount of information is logically appropriate for each situation.[511]

For example, doctors have a moral duty to respect patient autonomy but at the same time a professional moral duty to help the patients clinically which might clash with the patient's autonomous decision. When it comes to the doctor's moral duty to pass information and the inherent conflicts this has for patients, their approach to communication is guided by information the doctor would like to obtain from the patient and their ability to influence the patient through the information delivered. As a doctor myself, most of the communication in a clinical consultation appears to be clinically oriented. For example, it is usually based on

[510] Erica S Spatz, Harlan M Krumholz and Benjamin W Moulton, 'The New Era of Informed Consent: Getting to a Reasonable Patient Standard through Shared Decision Making' (2016) 315 The Journal of the American Medical Association 2063, 2064.

[511] Puteri Nemie Jahn Kassim, Fadhlina Alias and Ramizah Wan Muhammad, 'The Growth of Patient Autonomy in Modern Medical Practice and the Defined Limitations under the Shari'ah ' (2014) 22 IIUM Law Journal 213, 236.

medical work and the doctor's conduct is considered closely integrated into their medical decisions. Perhaps doctors do not usually carry this moral duty when communicating with patients. The information given is usually phrased to advise and direct the patients to the best option decided by the expert. Doctors might communicate treatment options 'selectively' to favour the patient's best interest but there is a danger of disregarding patients' personal reasons and autonomy. Thus, the duty of the doctor to disclose medical information is necessary for the patient to make an autonomous decision and should be applied universally, including in Malaysia. However, an ethical dilemma exists when the patient's choices conflict with what the doctor perceives to be in the patient's best interest.[512]

In Malaysia, the delivery of healthcare has traditionally been hierarchical and dominated by doctors as Malaysian patients tend to follow the doctor's orders without question. The suggested reason for this doctor-patient relationship in Malaysia is due to the power imbalance which is recognised in the Ethical Professional Practice Guidelines Academy of Medicine Malaysia.[513] It is claimed that within the doctor-patient relationship is the 'element of power'. 'The doctor has the training, the education, and the ability to treat the patient. All this acquired knowledge places the doctor in a position of power. The patient, not having the knowledge, understandably relies on the doctor to act in the patient's best interests'.[514] This is despite the patient's exclusive right to determine what they want to do or not do to their body and legal rights to determine the treatment the patients wish to undergo.[515] Thus, autonomy through informed consent has become a legal right involving patients and doctors as a protection for patients in case there is a failure to disclose adequate information and risk involved in the

[512] Ibid 229.

[513] Academy of Medicine Malaysia, 'Ethical Professional Practice Guidelines'.

[514] Ibid 45.

[515] Tengku Noor Azira Tengku Zainudin, Anita Abdul Rahim and Ramalinggam Rajamanickam, 'Consent to Medical Treatment and the Autonomous Power of Adult Patients: The Malaysian Legal Position' (2015) 6 Mediterranean Journal of Social Sciences .

proposed treatment. This development in the relationship between doctor and patient has relegated the need to obtain consent as part of a doctor's duty under the law of medical negligence.[516] This leads to a discussion of the patient's right not to know, in which a given piece of information is considered inappropriate or unnecessary to achieve a logical conclusion in a clinical decision.

The common law position on consent in Malaysia is well-defined but issues arise when patients are autonomous and competent, but doctors are unable to communicate and pass information to the full extent for the patients to make the right decisions and justify the decision. We discuss this issue and possible solutions through an ethical framework by arguing how these ethical principles of autonomy, beneficence and non-maleficence might justify the need for patient access to medical records.

The question arises as to whether the transmission of information that is provided verbally or through formal documents such as medical records has a commonality or difference and whether doctors gauge the adequacy of information according to different individuals' expectations and beliefs. The three acceptable legal (and moral) approaches to adequate information in an informed consent process are simplified into questions:[517]

1. **Subjective standard**: What would this patient need to know and understand to make an informed decision?
2. **Reasonable patient standard**: What would the average patient need to know to be an informed participant in the decision?
3. **Reasonable physician standard**: What would a typical physician say about this?

[516] Health and Safety Executive, 'Who Regulates Health and Social Care', accessed 20 May 2019.
[517] Shah and others, *Informed Consent*.

In informed consent, the key messages from *Montgomery* concerned what a patient would consider to be a material risk:

> The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.[518]

In Malaysia, these three standards were tested in the case of *Zulhasminar*. According to the Federal Court, when it comes to the standard of care in medical negligence cases, a distinction must be established between diagnosis and treatment and the responsibility to advise about risk.[519]

#### 5.2.1.1.3 Patient's right not to know

The right not to know is a concept within the principle of respect for autonomy[520] grounded in the acceptable practice for patients to make an autonomous decision as part of informed consent not to know information that is irrelevant, inappropriate or undesirable.[521] While several ethical precepts have been used in this discussion, autonomy is the most commonly cited by both proponents and opponents of 'the right not to know'. There are different views on the pros and cons of this right:

> Defenders of the right not to know typically employ a 'liberty' conception of autonomy, according to which to be autonomous involves doing what one wants to do, opponents of the right not to know often employ a 'duty'

---

[518] *Montgomery v Lanarkshire Health Board* [49].Lord Scarman summarised his conclusions at pp 889-890.
[519] *Zulhasnimar Hasan Basri & Anor v Dr Kuppu Velumani P & Ors* [2017] LNS 1057. In the case of Zulhasnimar, the Federal Court distinguished between the standards that apply to the duty to advise and the obligation to diagnose and treat. It was decided that the *Bolam* test still applied to the obligation to diagnose and treat (subject to the requirements in Bolitho). Regarding the duty to advise, doctors have a responsibility to inform and advise their patients about the relevant risks(subject to therapeutic privilege). This is a case where the doctor failed to perform an emergency caesarian section which led to the child developing cerebral injury.
[520] Torleiv Austad, 'The Right Not to Know - Worthy of Preservation Any Longer? An Ethical Perspective' (1996) 50 Clinical Genetics 85.
[521] Ben Davies, 'The Right Not to Know and the Obligation to Know' (2020) 46 Journal in Medical Ethics 300, 302.

> understanding, viewing autonomy as involving an obligation to be self-governing.[522]

Patients are obliged to have information about their health which influences decisions and self-management. However, autonomy should be exercised with freedom of will. With patients' increasing interest and involvement in self-care and health, it is natural that the right of individual patients to know personal information (including information in medical records) or possible complications of treatment should be emphasised. However, since this information might be extremely sensitive and burdensome, to make good clinical decisions individual patients must be given relevant and appropriate information. However, this might further encourage the doctor's patriarchal role in clinical decision-making as doctors may claim, or perceive, that particular information ought to be withheld due to potential harm such as mental distress.

With this argument in mind, a reference to the autonomy principle appears to be an adequate justification for the right not to know. According to Davies:

> A right not to know does not entail a right to be entirely ignorant, but neither does the value of autonomy imply a duty to maximise the control we exercise over our lives…..[523]

Similarly, Rhodes argues that:

> Patient is presumed to be an autonomous agent. Without the relevant information, the patient cannot make autonomous choice. From my point of view as individual autonomous agent….. when I choose to remain ignorant of relevant information, I am choosing to leave whatever happens to chance. I am following a path without autonomy. Now, if autonomy is the ground for my right to determine my own course, it cannot also be the ground for not determining my own course.[524]

---

[522] Ibid 137.

[523] Ibid 149.

[524] Rosamond Rhodes, 'Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge' (1998) 23 Journal of Medicine and Philosophy 10, 18.

Therefore, according to Rhodes, the right not to know is a personal and autonomous decision to refuse information.[525] Where knowledge may cause harm and good, or where the advantages are unclear, autonomy to freely decide what is the best (or kindest) course of action includes the decision not to know.[526] The right not to know is not an absolute concept in promoting respect for autonomy. The right of patients not to know should be balanced against individuals' right to know. This autonomy necessitates comprehensive and comprehensible knowledge, but no single individual can acquire information in totality. Again, we must look back at the legal and moral approach in which reasonable standards interplay. For example, a patient diagnosed with terminal cancer asks their physician for the prognosis and treatment and says explicitly that 'I do not want to die'. The doctor replies that the disease is incurable and that chemotherapy may slow down its progression. The doctor withholds the information that the median survival is 6 months with treatment to respect the right of the patient to not know that death is inevitable, without compromising the truth that the individual deserves to know that the disease is terminal (incurable). Evidence has shown that cancer patients crave information but they are often uncertain about what to know and sometimes unhappy with the information they receive.[527]

The patient's right not to know comes with implications, especially in informed consent. The 'doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments'[528] and yet patients often ask doctors to continue with treatment or investigation without wanting to know the potential complications. As long as the doctor documents this in the medical records so that other doctors who may treat the patient are

[525] Ibid 15.

[526] Tuija Takala, 'Genetic Moralism and Health' (2019) 28 Cambridge Quarterly of Helthcare Ethics 225, 228.

[527] Mark Drury and others, 'Patients with Cancer Holding Their Own Records: A Randomised Controlled Trial' (2000) 50 British Journal of General Practice 105, 105.

[528] *Montgomery v Lanarkshire Health Board* [87].

informed, and the patient can be given the choice to change their mind, the doctor will have respected the patient's autonomy not to know.

The type, interface and volume of information that doctors deliver during informed consent influences the traditional practice of information provided with space to further clarify and stratify based on the level of patient's understanding. However, this cannot always be guaranteed with the information provided in medical records, as the purpose of medical records is to facilitate communication between healthcare professionals, not patients.

### 5.2.2 Beneficence and non-maleficence

Turning to the second and third principles of principlism, beneficence and non-maleficence, it is best to discuss these concepts together and by using the concept of patient-centred care. These two principles provide an intricate relationship between doctors and patients when clear benefits versus potential harm interplay with wider access to medical records. The concept of patient-centred care is a model of patient empowerment to illustrate the partnership created between doctors and patients to produce positive patient-centred outcomes through self-management.[529] Patient access has the potential to improve patient-centred care delivery and may increase patient satisfaction but it can also add to the burden on the healthcare provider,[530] hence the need to explore both patients' and doctors' perspectives.

#### 5.2.2.1 The patient's perspective – Patient-centred care using the model of patient empowerment

Patient-centred care is a concept of building a mutually beneficial partnership between healthcare providers and patients at the heart of healthcare provision.[531] By forging this

[529] Mariastella Pulvirenti, John McMillan and Sharon Lawn, 'Empowerment, Patient Centred Care and Self-Management' (2014) 17 Health Expectations 303.
[530] Freda Mold and others, 'Patients' Online Access to Their Electronic Health Records and Linked Online Services: A Systematic Review in Primary Care' (2015) 65 British Journal of General Practice 141, 141.
[531] *Patient-Centred Care* (2019).

partnership, the concept has been developed to improve patient outcomes and experiences (beneficence) while reducing the burden of cost, unnecessary investigations and treatments (non-maleficence) and considering the patient's expectations and goals. In this thesis, the concept of patient-centred care with a specific model of patient empowerment aims to illustrate and enhance this doctor-patient partnership that is created to produce positive outcomes with minimal risks or harm by applying these principles. Personal health record platforms and patient portals can empower patients by providing access to medical records, but not all patients may be interested in this without the presence or support of their clinician.[532] Thus, the relationship, particularly from the viewpoint of benefits versus harm, is an intricate and delicate one that is relevant with wider access to medical records.

The WHO emphasised the idea of patient empowerment during the US civil rights movement in the 1950s and 1960s, pointing to the importance of citizen and community participation in their own health affairs.[533] Similarly, Gibson defined patient empowerment as a process of assisting people in gaining control over the factors that influence their well-being.[534] I also favour the proposition described by Aujoulat, D'Hoore and Deccache[535] that suggests patient empowerment has two dimensions: intra-personal and interpersonal. These dimensions will help motivate the patient and are both critical in forming the empowerment principle. The intra-personal dimension involves self-transformation. This factor can be improved by educating patients and increasing their understanding of their medical concerns.[536] The interpersonal dimension encompasses all experiences between a patient and a health professional that can

[532] Shadi Mossaed, Kevin Leonard and Gunther Eysenbach, 'Patient Preferences and Perspectives on Accessing Their Medical Records' (2015) 46 Journal of Medical Imaging and Radiation Sciences 205, 205.
[533] World Health Organisation and UNICEF, *Primary Health Care: Report of the International Conference on Primary Health Care*, (1978).
[534] Cheryl H Gibson, 'A Concept Analysis of Empowerment' (1991) 16 Journal of Advanced Nursing 354, 359.
[535] Isabelle Aujoulat, William d'Hoore and Alaine Deccache, 'Patient Empowerment in Theory and Practice: Polysemy or Cacophony?' (2007) 66 Patient Education and Counseling 13, 15.
[536] Ibid.

help the patient's self-esteem. Power is passed from one party to another in this manner and by sharing information, knowledge and decision-making, the health professional empowers the patient. Improving patient access, power and self-transformation are facilitated both intra- and interpersonally. [537] This is especially true when promoting shared decision making.

Shared decision making (SDM) has provided doctors and patients with a method of integrating professional advice with patients' preferences and goals to reach an informed decision.[538] Elwyn et al. describe SDM as a clinical practice that:

> rests on accepting that individual self-determination is a desirable goal and that clinicians need to support patients to achieve this goal, wherever feasible. Self-determination in the context of SDM does not mean that individuals are abandoned. SDM recognises the need to support autonomy by building good relationships, respecting both individual competence and interdependence on others.[539]

SDM in a consultation is inextricably linked to the principles of respect for autonomy. However, the core motivation for a clinical decision to be made is the ultimate goal of delivering and receiving high-quality patient-centred care with the lowest risk of complications or harm inherent to any medical treatment. Therefore, SDM also adheres to the principle of beneficence and non-maleficence.

Studies have consistently shown that SDM is linked to patient satisfaction with treatment outcomes and perception of personal control, decreased decision-making conflict, increased trust in providers and improved self-management and treatment adherence.[540] SDM can only

---

[537] Ibid.

[538] Alan J Fossa, Sigall K Bell and Catherine DesRoches, 'Opennotes and Shared Decision Making: A Growing Practice in Clinical Transparency and How It Can Support Patient-Centered Care' (2018) 25 Journal of the American Medical Informatics Association 1153, 1154.

[539] Glyn Elwyn and others, 'Shared Decision Making: A Model for Clinical Practice' (2012) 27 Journal of General Internal Medicine 1361, 1361.

[540] Fossa, Bell and DesRoches, 'Opennotes and Shared Decision Making: A Growing Practice in Clinical Transparency and How It Can Support Patient-Centered Care', 1154.

be effective when patients are empowered to increase their involvement in the process.[541] As a process in which a doctor and a patient collaborate to make a health choice, discussing the options, potential benefits and harms and the patient's values and preferences are key. Patient empowerment ensures that patients accept responsibility for their own health, which is essential for SDM. They can then learn to address their own health difficulties with the help of professionals and knowledge. Patient empowerment starts with the provider acknowledging that patients are ultimately in charge of their care and seeking to improve the patient's ability to think critically and make autonomous, educated health decisions.[542]

From a beneficence perspective, many definitions have been offered by scholars but to summarise, patient empowerment offers both freedom of choice and engagement in healthcare delivery to enhance equity of access to care, increase patient preference, improve patient access to health-related information, strengthen patient position in the healthcare system and promote greater knowledge sharing between patients and healthcare providers.[543] It allows patients to monitor their health-related symptoms and to be aware of the services available in the healthcare system to protect and encourage their well-being.[544] The association between patient satisfaction and health outcomes may be extrapolated to patients' ability to access, understand and use knowledge in respect of their health. Good health outcomes and patient satisfaction create a more trusting and enjoyable relationship between doctors and patients. Education is also known to be an independent predictor of access to medical records behaviour, as a higher level of education translates into better health literacy and healthcare decision-making.[545]

---

[541] Swetha Kambhampati, 'Shared Decision-Making and Patient Empowerment in Preventive Cardiology' (2016) 18 Current Legal Problems .

[542] Ibid 48.

[543] Rocco Palumbo, *The Bright Side and the Dark Side of Patient Empowerment* (Springer 2017)

[544] Ibid 4.

[545] Elske Ammenwerth, Petra Schnell-Inderst and Alexander Hoerbst, 'The Impact of Electronic Patient Portals on Patient Care: A Systematic Review of Controlled Trials' (2012) 14 Journal of Medical Internet Research e162, 9.

Patient empowerment has been increasingly recognised in the UK as a central strategy for upholding the right of patients to appropriate and fair care. The UK's NHS has recently published a review on 'Empowering patients through their personal record' [546] which aims to identify the factors that lead to patient empowerment through digital technologies. On the other hand, the House of Care model was developed as a framework to achieve person-centred care which includes 'engaged, informed individuals and carers' as one of the components to enable individuals to self-manage and know how to access services.[547] Furthermore, a study was performed and one of the surprising findings was that, despite clear legislation which enables patients to access their medical records, 37% did not know they had this right[548] which may be rooted in the lack of patient empowerment. These numbers are similar to those from a 1986 study by Baldry et al., who asked patients whether they read their paper records: 30% of the 23 non-readers (6.9% of the total respondents) felt that 'it was not their place to read their records'.[549] One might have anticipated that patient empowerment would have advanced more in the intervening 25 years.

In Europe, the Picker Institute has developed a policy on Person-Centred Care in Europe as part of an approach to:

> Empower[ing] the patient by expanding their role in their healthcare. Making the patient more informed and providing reassurance, support, comfort, acceptance, legitimacy and confidence are the basic functions of this approach. Person-centred care assumes that patients are qualified to decide their own needs and expectations and that they are able to make decisions and choices about what they need and want: the role of healthcare providers is therefore to

[546] Gabriel Mata-Cervantes, Charlotte E Clay and Craig Baxter, *Empowering Patients through Their Personal Health Record*, (2016), 1.
[547] NHS England, 'House of Care – a Framework for Long Term Condition Care' <https://www.england.nhs.uk/ourwork/clinical-policy/ltc/house-of-care/>, accessed 15 November 2022
[548] Mossaed, Leonard and Eysenbach, 'Patient Preferences and Perspectives on Accessing Their Medical Records', 210.
[549] Molly Baldry and others, 'Giving Patients Their Own Records in General Practitioner: Experience of Patients and Staff' (1986) 292 British Medical Journal 596, 598.

support patients with appropriate health advice so that they can make informed decisions about their own treatment.[550]

The NHS has also launched the 'Expert Patient Programme' to engage patients in the healthcare delivery system through the establishment of a partnership between patients and providers of care.[551] This scoping review outlined potential benefits of patients accessing their personal health records including:

1. Reinforcing the vicious cycle of patient activation, engagement and empowerment.
2. A strong association between a patient's level of engagement and intention to use a personal health record.
3. Engaged individuals may have better health outcomes.
4. Reported consequences of patient empowerment such as independence, increased knowledge, increased self-esteemed and increased confidence in collaborating with their doctors.
5. Patients feeling more in control of their healthcare with better self-awareness.
6. There is evidence to suggest that access is more useful to those with chronic as opposed to acute conditions.[552]

Similar initiatives have taken place across the US, where patient empowerment is fostered through the movement of OpenNotes.[553] Around 20,000 patients were invited to read notes online through patient portals by 105 primary care physicians at three US healthcare facilities

[550] Giuseppe Paparella, 'Person-Centred Care in Europe: A Cross-Country Comparison of Health System Performance, Strategies and Structures' (*Picker Insitute Europe,* 2016) <https://www.basw.co.uk/system/files/resources/basw_100601-9_0.pdf>, accessed 10 May 2020. See page 2.
[551] National Health Service, 'The NHS Expert Patient Programme (NHS EPP) Where Next and Its Relevance for Other Health Care Systems' (2018), accessed 10 May 2020.
[552] Ibid.
[553] Tobias Esch and others, 'Engaging Patients through Open Notes: An Evaluation Using Mixed Method' (2016) British Medical Journal 1, 5-6.

as part of the OpenNotes initiative's year-long demonstration experiment in 2010. Increasing patient understanding through information seeks to encourage patient activity and participation, which improves patient health control.[554] Shared notes, according to studies, enhance patient-doctor communication, safety and relationships, which may encourage people to take a more active role in their health.[555] It is crucial to the conversation about patient empowerment and demonstrates how a simple intervention can have an enormous impact that leads to multiple benefits therefore promoting the act of beneficence.

#### 5.2.2.2 The doctor's perspective – Paternalistic non-maleficence

I have argued that informed consent is one of the better ways of achieving respect for autonomy and that valid informed consent must include information that is relevant and significant and leads to a logical clinical decision shared by doctors and patients to promote beneficence. However, a patient's right to be informed, which is protected under the legal requirement of informed consent, may come into conflict with the doctor's duty to protect the best interest of the patients under their care. Historically, this was recognised in the Hippocratic Oath 2,500 years ago which stated that medical practitioners must take care to ensure that ethical practices are followed in situations where 'it was primarily their responsibility to conclude what would be best for the patient without necessarily involving them in the choices'.[556] The Oath advocated that the doctor should not disclose anything to the patient that may worsen the patient's condition.[557]

This position, while patriarchal, still exists in the practice of medical paternalism and therapeutic privilege because, like the Hippocratic Oath, it is not to disclose information that

554 Ibid 5-6.
555 Ross and Lin, 'The Effects of Promoting Patient Access to Medical Records: A Review', 133.
556 Veronica English, *Medical Ethics Today: The Bma's Handbook of Ethics and Law* (2nd edn, 2004), 25.
557 Joram Graf Haber, 'Patients, Agents and Informed Consent' (2013) 1 Journal of Law and Health 43, 53.

may cause harm to the patient. The current legal standard in all jurisdictions for medical ethics and law requires doctors to keep patients from harm but also 'respect the rights of patients to be fully involved in decisions about their care'.[558] However, in the context of a doctor and patient relationship, 'the notion that patients have a moral claim to direct the course of their own medical care and to be given reasonably full information to make medical decisions is the most significant challenge of the bioethics movement to conventional medicine'.[559] Although there is an emphasis on autonomy, it is still a principle which might be overridden in the interests of non-maleficence if the information might be harmful to the patient. Therefore, one of the core levers of a successful doctor-patient relationship leading to a clinical decision is communication. I will explore this concept as a basis to support the doctor's perspective in continuing the practice of medical paternalism and therapeutic privilege to support non-maleficence.

It is the duty of the doctor in a doctor-patient communication[560] to disclose medical information selectively and withhold certain information which includes prognostication or information that might cause harm mentally or physically to patients that can make autonomous decision-making more difficult and less valid. Doctors might communicate selectively, either by being selective in their questioning, to funnel the patient to a certain diagnosis, or selectively promoting the treatment options that reflect the patient's best interest. However, there is a real concern that patients' personal expectations and autonomy could be eroded as a consequence.

This section discusses the complexity involved in how doctors transmit and receive information, as they may have their own reasons to not disclose information verbally. Evidence has shown that doctors tend to be selective in their communication to steer patients towards the

---

558 English, *Medical Ethics Today: The Bma's Handbook of Ethics and Law*, 15. English, *Medical Ethics Today: The BMA's Handbook of Ethics and Law*, 15.

559 Elias Baumgarten, 'The Concept of Patient Autonomy' (1999) 2020 Medical Updates 1.

560 Horton, 'Accountability and Time', 131.

decision they deem the most appropriate and in the patient's best interest.[561] Doctors also avoid discussing the emotional and social effects of their patients' illnesses because they are not resourced to appropriately address these concerns due to time constraints and lack of training in counselling.[562] Patients may also be hesitant or decline to report health difficulties as a result of these selective questions, which may cause their recovery to be delayed or result in an un-holistic approach, leading to less successful outcomes for the patient.[563] For example, sexual health is not a routine part of a consultation in chronic conditions such as cardiovascular disease and diabetes and is therefore frequently overlooked. However, studies have shown that addressing this aspect of health is beneficial for patients.[564]

It is therefore essential that doctors, while respecting patient autonomy, explore patients' preferences to receive selective information and make shared decisions without any pre-emptive assumptions. What this suggests is that beneficence and non-maleficence are key components to answering the question of widening access to medical records which should be selective, like the doctor's role in communication.

Emanuel and Emanuel provide a nuanced set of observations of the doctor-patient relationship involving the doctor's role in the four dimensions of communication and how it relates to the patient's autonomy. Referred to as the 'four models of the physician-patient relationship', they are the informative model, the interpretive model, the deliberative model and the paternalistic model.[565] The informative model, also known as the 'consumer model' aims to provide patients

---

561 Aditya K Ghosh, Shashank Josh and Amit Ghosh, 'Effective Patient-Physician Communication – a Concise Review' (2020) 68 Journal of the Association of Physicians of India 53, 57.

562 Georgia Hardavella and others, 'Tip Tops to Deal with Challenging Situations: Doctor–Patient Interactions' (2017) 13 Breathe 129, 132.

563 Jennifer Fong Ha and Nancy Longnecker, 'Doctor-Patient Communication: A Review' (2010) 10 The Ochsner Journal 38, 39.

564 Catherine Lim and others, '"It Just Seems Outside My Health": How Patients with Chronic Conditions Perceive Communication Boundaries with Providers' (HHS Public Access)

565 EJ Emanuel and Linda L Emanuel, 'Four Models of the Physician-Patient Relationship' (1992) 267 The Journal of the American Medical Association 2221, 2221-2222.

with all relevant information so that they can choose the medical intervention they want. Patients have access to all medical information relevant to their disease and the concept of patient autonomy allows total patient control over clinical decision-making. The interpretive model seeks to clarify and explain patients' values to choose which medical action is best for them. Doctors recreate a patient's goals, values and priorities, then assess which treatments are most effective in realising those objectives. This strategy necessitates the patient being fully involved in a shared process of understanding and decision-making. The deliberative model is where the physician acts as a teacher or friend, engaging the patient in a dialogue on what course of action would be best, in which the physician advises what the patient should do. As a result, the goal is not just moral persuasion, but patients must engage in active discussion about health-related objectives that they could and should pursue. In the paternalistic model, patients receive the interventions determined by the doctor who may provide the patient with carefully selected information to persuade them to consent to the intervention that the doctor believes is the most appropriate. With limited patient participation, it is up to the doctor to decide what is in the best interests of the patient. Some form of paternalistic model continues to practise worldwide in agreement with Schneider who argued that:

> While patients largely wish to be informed about their medical circumstances, a substantial number of them do not want to make their own medical decisions, or perhaps even to participate in these decisions in any significant way.[566]

These brief illustrations show how different models assume that patients will experience different information transmission depending on the nature of the doctor-patient relationship. This relates to medical records and how access can provide another mode of information transmission, albeit an inflexible one (in which empathy, clarification and avoidance of medical terms can take place in a clinical consultation but not from medical records alone). It is clear

[566] Carl E Schneider, *The Practice of Autonomy: Patients, Doctors and Medical Decisions* (Oxford University Press 1998).

that, except for the paternalistic model, improving patient access is conducive to the environments these models seek to facilitate by transmitting more information to engage patients as much as possible in decision-making.

#### 5.2.2.2.1 Medical paternalism

As communication plays a role in determining the outcome of patients' medical care, it helps us to discuss the distinction between the doctor's paternalistic role versus the patient's non-maleficence. However, I would like to introduce an alternative concept in which the notions of paternalism and patient non-maleficence are joined in practice as 'paternalistic non-maleficence'.

Paternalism is analogous to the parent-infant relationship and in line with *primum non nocere* (first do no harm) that has become the core principle of medical ethics and the doctor-patient relationship.[567] The doctor's role to act in the patient's best interest is stated in the Declaration of Geneva: the 'health of my patient will be my first consideration'.[568] However, this has the potential to reduce the patient to a submissive or passive role.[569] Paternalism is 'interference with a person's liberty of action justified by reasons referring exclusively to welfare, good, happiness, needs, interests or values of the person being coerced'.[570] In medical paternalism, the term refers to 'interference by the doctor with the patient's freedom of action which is justified on the grounds of the patient's best interests'.[571]

Medical paternalism based on the principles of beneficence and non-maleficence may at times override the principle of autonomy. For example, a doctor's refusal to execute an action

[567] Ama K Edwin, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege - Is It Ever Justified?' (2008) 42 Ghana Medical Journal 156, 156.
[568] Baumgarten, 'The Concept of Patient Autonomy'.
[569] Edwin, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege - Is It Ever Justified?'
[570] Gerald Dworkin, 'Paternalism' (1972) 56 The Monist 68.
[571] Gary B Weiss, 'Paternalism Modernised' (1985) 11 Journal of medical Ethics , 184.

requested by a patient because it would not be beneficial and might even be harmful to the patient could be considered paternalistic. While not performing an act that produces benefits is not necessarily immoral, an act not performed in the interests of non-maleficence is considered immoral and the doctor here has completed an action that can be described as paternalistic non-maleficence in which they exercise a paternalistic approach to avoid harm by eroding the patient autonomy in the name of the patient's best interest.

For example, an elderly male patient with multiple comorbidities diagnosed with liver failure is informed that there is no cure. However, he returns to his doctor and requests referral to a liver transplant programme although his chance of death during the transplant is high due to his age and co-morbidity. By refusing to refer him to a transplant programme, the doctor has performed an act of paternalistic non-maleficence and eroded the patient's autonomy. In contrast, if the doctor refers the patient to the transplant programme clearly understanding that this act was futile, he could be described as acting immorally as he has failed to act non-maleficently by allowing the patient to pursue an unrealistic expectation and adding to the waiting list for the transplant programme that is essential for those who would clearly benefit.

To explore the concept of paternalistic non-maleficence, it is important to revisit the theory of harm in medical practice. Harm itself is not clearly defined in clinical practice. The WHO definition includes 'temporary or permanent impairment, suffering, disability or loss in function or structure, which can be physical, emotional, financial or psychological and also includes death'.[572] Beauchamp and Childress described harm as normative or non-normative. Normative is a standard type of harm which is 'spontaneously' accepted by every moral person while non-normative harm is incurred without the notion of 'wrongdoing'[573] (see Section

[572] World Health Organisation, 'The Conceptual Framework for the International Classification for Patient Safety' (2009) <https://onlinelibrary.wiley.com/doi/full/10.1111/jocn.13378>, accessed 8 January 2020.
[573] Beauchamp and Childress, *Principles of Biomedical Ethics*, 153.

4.3.2.2) to include mental distress, poor judgement and poor decision-making when informed of bad news. Epicurus stated that harm is necessarily experiential and therefore must be experienced to be considered as harm.[574] One can argue that the harm proposed in paternalistic non-maleficence is theoretically experiential (mental distress over bad news) however, might be confirmed as non-experiential when the deed has been acted upon (the delivery of bad news). Therefore, it is more difficult to justify paternalism based on a judgement that may serve the self-interest of a doctor, who can only presume the best interest of a patient using his or her professional judgement.

In the late 1980s, the concept of paternalistic beneficence was introduced but not widely discussed in medical practice.[575] I propose that this is different from paternalistic non-maleficence, precisely due to the moral obligation attached to the act of non-maleficence. A doctor-patient relationship usually emphasises positive outcomes (beneficence), including curing diseases, and improving health and lifespan, weighing the balance between treatment and potential complications as an everyday art in a clinic consultation. For example, a 52-year-old lady with a critical illness presenting to the emergency department is sent to the ICU without her permission due to the lack of capacity and time to discuss the treatment plan with her. The doctor acts in the patient's best interests without her explicit permission (paternalistic beneficence) to potentially save her life. However, this situation could be reversed if a 92-year-old lady arrived with the same presentation. It is well-established in critical care medicine that at that age there is a poor prognosis for survival and might cause more suffering to a patient. The doctor opts for symptomatic management and palliation without discussing it with the

[574] *Epicurus (341—271 B.C.E.)*

[575] Marcia Abramson, 'Autonomy vs. Paternalistic Beneficence: Practice Strategies' (1989) 70 The Journal of Contemporary Social Work .

patient who is incapacitated. Here, the doctor has performed an act of paternalistic non-maleficence in line with their duty and professional judgement.

Thus, there is a conflict of interest between the patient's autonomy and the inherent nature of medicine that can be paternalistic, with the latter eroding the former. This is important in relation to patient access because it is the element of autonomy and right to self-determination that should justify wider access to medical records. The constant collision between a doctor's professional autonomy and the patient's autonomy translates to many of the discussions that apply to matters of accessing medical records.

#### 5.2.2.2.2 The doctor's autonomy and therapeutic privilege

In addition to medicine being inherently paternalistic, two other significant factors from the doctor's perspective are professional autonomy and therapeutic privilege.

A doctor's autonomy is considered professional autonomy, 'the legitimate control that the members of an occupation exercise over the organisation and the terms of their work'.[576] This means that doctors have control over decisions in their clinical work and can provide care to patients.[577] As a doctor becomes more experienced and moves into positions of senior clinical leadership, they are given more opportunities to exercise their autonomy given their experience and expert knowledge. This empowerment helps to develop their healthcare institution towards a certain goal using professional authoritative persuasion due to the privilege of enjoying a high status in the healthcare hierarchy. For example, a highly trained transplant physician is developing a new transplant service for a specific area and using clinical leadership and best evidence, runs the transplant service as he sees fit as he had earned this authority to practice

[576] Domenico Salvatore, Dino Numerato and Giovanni Fattore, 'Physicians' Professional Autonomy and Their Organizational Identification with Their Hospital' (2018) 18 BMC Health Services Research 1, 2.
[577] Ibid 3.

his autonomy. The arduous training in medicine naturally creates hierarchical power that promotes patriarchal practices in such instances.

Under professional autonomy, it might be acceptable for doctors to use their authority to decide whether certain information can cause harm and should be withheld from patients. Since doctors must act beneficently, it is the doctor's professional autonomy to act with discretion to determine any exemptions from information disclosed to patients, including in medical records. This issue of exception from disclosure is illustrated in *Canterbury v Spence*:

> It is recognised that patients may become so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder treatment, or perhaps even pose psychological damage to the patient. Where is that so, the cases have generally held that physician is armed with privilege to keep the information from the patient and we think it is clear that portents of that type may justify the physician in action he deems medically warranted.[578]

This statement leads to another practice in withholding information relevant to access; therapeutic privilege.

> Withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient. Although it is thought that the failure to tell the truth in the context of the doctor-patient relationship is an essential part of therapy, it is doubtful whether a doctor is proficient or justified in making a value judgement about what is best for a competent patient. A competent person is an adult of sound mind and body. As Justice Cardozo memorably puts it: 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body'.[579]

Therapeutic privilege is exercised as part of the fundamental ethical principle of 'non-maleficence' to deny a patient access to information, including that contained in medical records, which would adversely affect the patient's mental or physical well-being.[580] As

---

578 *Canterbury v Spence* [1972] 464 F2d 772783. At 783.

579 *Schloendorff v Society of Ny Hospital* [1914] 105 NE 92.

580 Hayley Rosenman, 'Patients' Rights to Access Their Medical Records: An Argument for Uniform Recognition of a Right of Access in the United States and Australia' (1997) 21 Fordham International Law Journal 1550, 1522.

common justifications for non-disclosure include disclosure which 'would create incapacitating emotional distress and that disclosure would violate a patient's personal, cultural, or other social requirements',[581] withholding certain information is an act in the patient's best interests and is performed to do no harm (non-maleficence).

Therapeutic privilege is formulated differently among different institutional practices and legal jurisdictions[582] and can, of course, be extended to medical records. For example, doctors may enter a list of differential diagnoses in a medical record, but an exhaustive list is not usually shared with patients as this may create unnecessary anxiety and confusion. In other circumstances, doctors might withhold information if the patient's knowledge of the information would have serious health consequences which may compromise a treatment's success and impede relevant decision-making. As there are no definitive guidelines on how therapeutic privilege should be exercised, this acceptable routine causes doctors to withhold information if disclosing it could worsen the patient's condition. Hence, therapeutic privilege is controversial because the status of the doctrine lacks clarity (see Chapter 7).

There is legal recognition of this practice but we can argue that it is not applicable on ethical grounds. This is because the concept of therapeutic privilege transcends the concept of access, in which restricting access to the information within medical records should not be ethically justified. The equation should be simple; when a doctor takes a paternalistic approach, the patient loses their autonomy. Patients who are unable to make their own decisions thus remove themselves from all responsibility for their health. However, a doctor's decision to forego their expertise and give the patient complete autonomy may be a violation of their own professional

[581] Emily B Rubin, *Handbook of Clinical Neurology* (2013).

[582] Emma Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception' (2017) 46 Common Law World Review 140, 160.

ethics and the Hippocratic Oath's medical code.[583] Choosing not to force their choices on patients would also breach the doctor-patient relationship as it is the doctor's duty to advise and ensure that decision-making produces good outcomes.[584]

## 5.3 Conclusion

In the last chapter, I discussed the main ethical theories used in medicine to provide a context for the debate on widening patient access that will be considered in the next chapter. Having briefly outlined utilitarianism and deontology, I considered the best-known ethical framework in clinical practice: Beauchamp and Childress's four principles of autonomy, beneficence, non-maleficence and justice. In this chapter, I then used the framework of principlism to illustrate important analogies such as informed consent, doctors as information providers, patient empowerment, medical paternalism and therapeutic privilege in which the principles of autonomy, beneficence and non-maleficence are exercised based on both the patient's and doctor's perspectives respectively. The framework argued in this chapter is then applied to answer why patient access to medical records should be widened using the platform of ethical and legal necessity.

I demonstrated that the onus and responsibility are on the doctor to uphold the principles to 'promote good' and 'do no harm' in line with respecting the patient's autonomy. The principle of autonomy, in its ethical form, provides a strong ethical justification in the context of informed consent. Legal necessity was thus an outcome or at least an associate of ethical

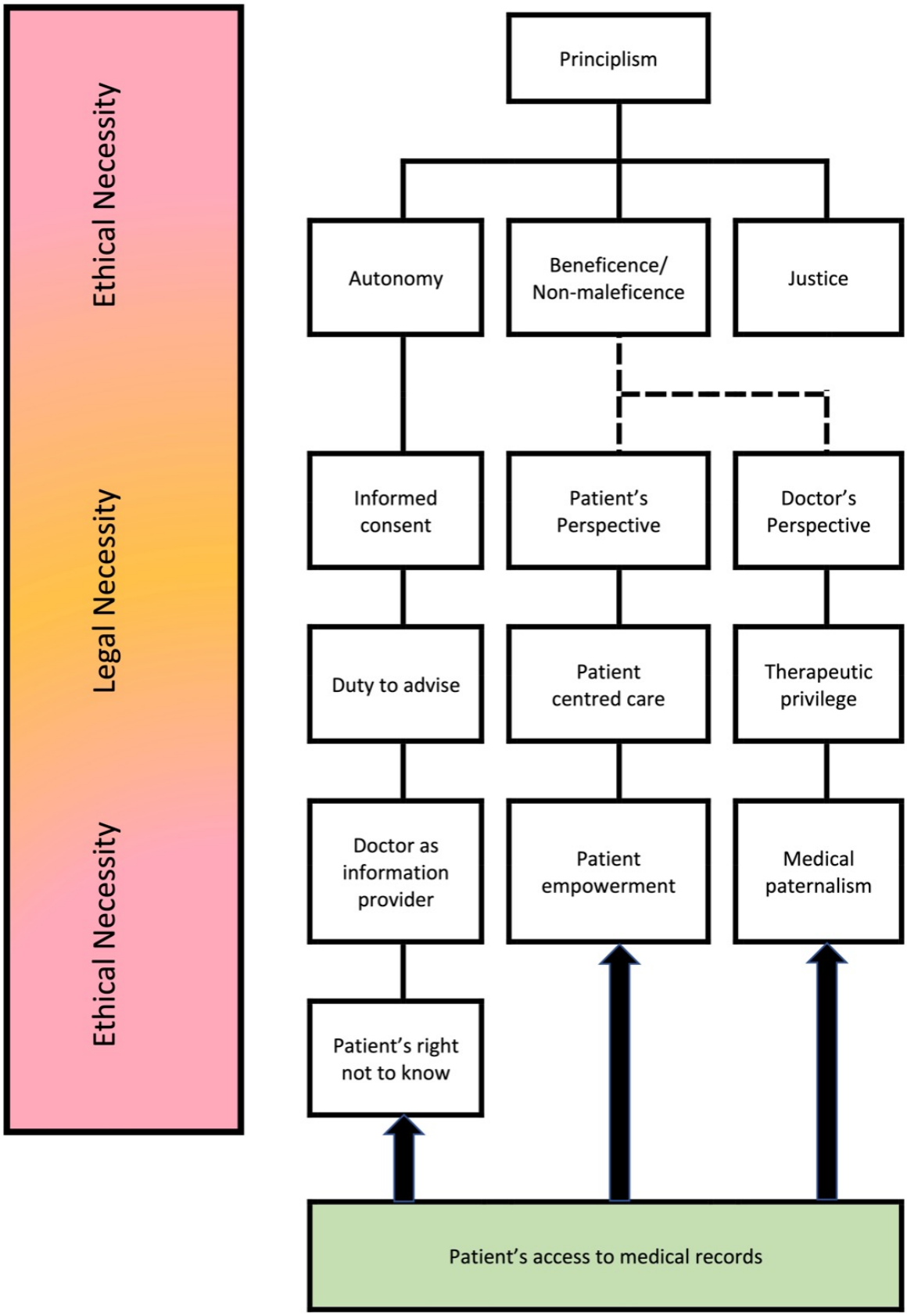
583 Vishal I India and MS Radhika, 'Hippocratic Oath: Losing Relevance in Today's World?' (2019) 61 Indian Journal of Psychiatry , 774.

584 Tre LaRosa, 'Exploring Autonomy and Paternalism in the Doctor-Patient Relationship' (*Cystic Fibrosis News Today,* 2020) <https://cysticfibrosisnewstoday.com/columns/autonomy-paternalism-doctor-patient-communication/#:~:text=An%20abstract%20spectrum%20exists%20between,the%20patient%20loses%20all%20autonomy.>, accessed 20 September 2020.

necessity, or imperative, which makes informed consent the cornerstone of medical ethics and provides the basis for the discussion in the next chapter.

Thus, respect for autonomy is an important element to justify legal requirements and recognition of patients' right to information. Informed consent should also stipulate allowing access to information in medical records, as this allows the patients to be more informed and make better decisions. In the context of informed consent, in which comprehensive information is required, I also emphasised promoting respect for autonomy by discussing the doctor's duty to advise and to be an information provider. Inextricably linked to respect for autonomy is beneficence, in which I discussed patient-centred care using the model of patient empowerment to produce positive outcomes from the patient's perspective. However, I also elaborated on the doctor's perspective using the principle of non-maleficence that drives the prevailing practice of medical paternalism and therapeutic privilege. These common but important themes are illustrated in Figure 5-1 and used to form the basis of the debate and answer the research question of whether Malaysia should widen patient access.

**Figure 5- 1: Important parallel analogy of themes in relation to patient access**



# Chapter 6. Patient access to medical records – Should Malaysia widen access?

## 6.1 Introduction

In this chapter, I use the discussion and arguments outlined so far to justify wider patient access to medical records, based most importantly on the patients' perspective followed by the doctors' perspective.

The MMC and case law have recognised a patient's right to access medical records.[585] However, as discussed in Chapter 2, regulation on this issue appears inconsistent and has led to patient access being granted only if a court order has been obtained. There is a complex regulatory space that leads certain practices and values to prevail including medical paternalism and therapeutic privilege, compounded by the effects of the high status that doctors enjoy in the doctor-patient relationship.[586] While there is no empirical evidence to suggest this effect, there is limited discussion on issues such as clinical governance and patient-centred care in Malaysia, as discussed in Chapter 3. These practices are already well-established in the UK, comparison with which only highlights the lack of progress concerning autonomy issues, including access to medical records, in Malaysia. While patient access is increasingly accepted in healthcare systems such as in the UK, this thesis addresses the deficit in scholarship by scrutinising and analysing this important issue for Malaysia. After comparing the regulations between the two countries and discussing the ethical theories that shape and influence everyday

[585] Refer to Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports* .
[586] Wendy Lipworth and others, 'Doctors on Status and Respect: A Qualitative Study' (2013) 10 Journal of Bioethical Inquiry 205, 205.

clinical practice in information transmission, I will now turn to the central research question of patient access to medical records and whether Malaysia should widen it.

## 6.2 Ethical theories to justify wider access to medical records

In Chapter 4, I discussed two types of patient access (See Section 4.1). The first is direct and immediate access which usually covers all electronic data including a patient's demographics, clinical notes and investigation results and are accessible by patients at any time or place. OpenNotes in the US is the most established example that encourages healthcare professionals to share clinical visit notes with patients, facilitating patients' legal right to access medical records in real time.[587] The second is automatic access to medical records which is unrestricted access without a legal approach or lengthy bureaucratic process, in which an autonomous and competent patient's request to access their medical records is granted automatically, albeit with the caveat that there may be instances where access cannot be immediate or direct.

As obtaining medical records in Malaysia requires a court order and is based on both legal and ethical considerations, I have previously discussed that ownership, access and control of medical records are influenced mainly by the doctors and hospital providers. Therefore, I will focus on the second type of access – automatic access.

As introduced in Chapter 5, the ethical theories of utilitarianism and deontology can be used to form ethical justifications to answer the research question. However, I will rely heavily on principlism as the prominent framework in answering the question. This will show how both utilitarianism and deontology agree on the conclusion to widen patient access. The contribution of each ethical theory is:

[587] Refer to Fossa, Bell and DesRoches, 'Opennotes and Shared Decision Making: A Growing Practice in Clinical Transparency and How It Can Support Patient-Centered Care'.

1. Utilitarian justifications widen access to maximise benefits.
2. Deontological justifications are grounded in the notion that 'restricting' access is inherently immoral.
3. Principlism uses autonomy, beneficence and non-maleficence to provide both arguments for and against widening access.

### 6.2.1 The utilitarian approach to justify wider access to medical records

In utilitarianism or consequentialist theory, decisions are made based on an outcome that will produce the greatest amount of benefit for the greatest number of individuals.[588] Therefore, the morality of an intervention is determined by its consequences.[589] However, while the aim is the maximum benefit, the approach could lead to undesirable effects for some individuals.

The main reason why legislation and national guidelines in various countries mandate that patients should be able to readily access their medical records is for the same underlying purpose; respect for patient autonomy. While autonomy is not an element of utilitarian theory, its value is essential to the individual because it determines their ability to act according to their own interests and values. It is thus a utility as it drives one's involvement and innovation[590] to achieve what is perceived as positive and beneficial by the individual, which subsequently extends to the institution, community and society. Respect for patient autonomy has become a primary tenet of medical ethics[591] as it is a desirable outcome for patients to have their values and beliefs involved in the self-determining process of clinical decision-making. Other

---

588 Amer, 'Understanding the Ethical Theories in Medical Practice', 189.

589 Peter Mack, 'Utilitarian Ethics in Healthcare' (2004) 12 International Journal of The Computer, the Internet and Management , 68.

590 Joan Cheverie, 'Why Autonomy Is Important for Peak Performance?' (2015), accessed 26 September 2020.

591 John Coggon and Jose Miola, 'Autonomy, Liberty and Medical Decision-Making' (2011) 70 Cambridge Law Journal , 523. Although there are those who question the extent to which autonomy should be treated as a primary tenet of medical ethics – for an example of this see, Angus Dawson, 'The Future of Bioethics: Three Dogmas and a Cup of Hemlock' (2010) 24 Bioethics 218.

potential benefits are outlined in the NHS 'Empowering patients through their personal record'[592] review such as patients feeling more empowered and engaged, resulting in better health outcomes. However, it is important to consider the outcomes, or consequences, of improved patient access using empirical evidence to support this theory. As utilitarian theory is entrenched in happiness and benefits, I will briefly discuss some empirical studies that report the effects of patient access, summarised in Table 6-1. As decisions under utilitarianism are made seeking the result that will create the greatest amount of benefit for the greatest number of people, I will now discuss the empirical evidence to support and weigh these 'benefits'.

Britten et al.'s study was conducted in London where patients and consultants were selected for interviews.[593] Consultants who criticised patient access claimed that patients would be perplexed with the information, as they were unfamiliar with the medical terminology and language. They also said that they would have to redact any material that has any degree of subjective views as the notes were written for doctors to establish a private dialogue amongst themselves. Lee et al. conducted a study of patient notes to identify barriers to patient access to medical records and found that those which confused patients, generated offence or had an impact on perceptions and professionalism were those that used medical words with judgemental connotations, errors and the use of jargon.[594] For example, in the section on the patient's history, it is often a necessity to enquire about sexual orientation, particularly with an HIV-positive patient. An entry stating the patient is homosexual, although written non-judgementally and without ill intent, may be uncomfortable or create undue stress for the

[592] Mata-Cervantes, E Clay and Baxter, *Empowering Patients through Their Personal Health Record*.
[593] N Britten and others, 'Consultants' and Patients' Views About Patient Access to Their General Practice Records' (1991) 84 Journal of the Royal Society of Medicine 284.
[594] Eric Hweegeun Lee, Jay Pravin Patel and Auguste Hector Fortin 6th, 'Patient-Centric Medical Notes: Identifying Areas for Improvement in the Age of Open Medical Records' (2017) 100 Patient Education and Counseling 1608, 1608.

patient as he may perceive that his infection is considered a punishment for his sexual orientation.

Fisher et al. [595] examined cancer patients' reactions and doctors' preconceptions of patient access to medical records and the reality of access provided to both parties using semi-structured interviews. The results showed that patients who chose to look at the records found them helpful and reassuring, despite information about a bad prognosis. Doctors expected that access would cause harm to patients but did not wish to amend the entry. The majority of doctors expressed negative opinions, listed in four main categories: the worry that patients would be harmed and upset by the information received; that patients would misinterpret the content and therefore more time would be required to explain the technical terms; the timing of the release of information which might be inappropriate; and that access might expose doctors as uncertain and prone to error.[596]

Weinart et al. [597] distributed questionnaires in an academic hospital to evaluate the response to a trial of giving patients daily 'progress notes'. They reported that a range of 74 to 86% of patients responded favourably as it improved their understanding and feeling of control, while 9-28% of healthcare providers felt that they were more careful with what they wrote in the 'progress notes' and 72% said the contrary. However, as this was based in one centre with a small number of participants (75 patients and 12 providers), this study is limited due to its lack of external validity.[598] The impact on doctors was claimed to be acceptable; however, the

[595] B Fisher and Nicky Britten, 'Patient Access to Records: Expectations of Hospital Doctors and Experiences of Cancer Patients' (1993) 43 British Journal of General Practice 52, 53.
[596] Ibid 53. Craig Weinert, 'Giving Doctors' Daily Progress Notes to Hospitalized Patients and Families to Improve Patient Experience' (2017) 32 American Journal of Medical Quality 58.
[597] Weinert, 'Giving Doctors' Daily Progress Notes to Hospitalized Patients and Families to Improve Patient Experience', 60.
[598] Ibid 60.

doctors reported taking longer and were cautious with the style of documentation to address how a patient or family could react.

**Table 6-1: Summary of empirical evidence**

| Author | Title | Summary of results |
|---|---|---|
| Britten et al., 1991 | Consultants' and patients' Views About Patient Access to Their General Practice Records | The result shows that patients were perplexed by the material, according to critics of patient access, because they are inexperienced with medical terms. |
| Fischer et al., 1993 | Patient Access to Records: Expectations of Hospital Doctors and Experiences of Cancer Patients | The results showed that patients who chose to look at the records found them helpful and reassuring despite information about a bad prognosis. Doctors expected that access to cause harm to patients but did not wish to amend the nature of the medical entry. |
| Wibe et al., 2011 | Lay People's Experiences With Reading Their Medical Record | The study discovered that patient reasons for requesting records include a desire for control, taking responsibility and examining inaccuracies. |
| Pagliari et al., 2012 | Embedding Online Patient Record Access in UK Primary Care: a Survey of Stakeholder Experiences | Most clinicians and patients believed that the service had improved mutual trust, communication, patients' health knowledge and health behaviour and patients have reported that they are feeling more involved with the treatment. |
| Han Li et al., 2014 | Examining the Decision to Use Standalone Personal Health Record Systems As a Trust-Enabled Fair Social Contract | PHR stressed the importance of trust as an essential element of a social contract governing the exchange of information in a personal health record. |
| Crouch et al., 2015 | A Pilot Study To Evaluate The Magnitude Of Association Of The Use Of Electronic Personal Health Records With Patient Activation And Empowerment In HIV-Infected Veterans | Patient activation was found to be linked to an increase in the use of personal health records. Patient empowerment is recognised to be preceded by both patient engagement and patient activation. |
| Toscos et al., 2016 | Impact Of Electronic Personal Health Record Use On Engagement And Intermediate health outcomes Among Cardiac patients: A Quasi-Experimental Study | In patients with coronary artery disease, researchers assessed patient adoption of a personal health record and its impact on patient participation and health outcomes. They discovered that patient engagement and the intention to use a personal health record are strongly linked. |
| Lee et al., 2017 | Patient-Centric Medical Notes: Identifying Areas For Improvement In The Age Of Open Medical Records | According to the study, the notes that confuse patients, generate offence or have an impact on perceptions and professionalism were those that used medical words with judgemental connotations, errors and the use of jargon. |
| Weinert et al., 2017 | Giving Doctors' Daily Progress Notes To Hospitalised Patients And Families To Improve Patient Experience | While 28% of healthcare providers felt that they were more prudent with the clinical entry in the 'progress notes', 72% disagreed that the idea affected their practice. However, as this was based in one centre with a small number of participants (patient=75, provider 12), this study is limited due to the lack of its external validity. |
| Rathert et al., 2017 | Patient-Centred Communication In The Era Of Electronic Health Records: What Does The Evidence Say? | Patient access to the EHR and messaging functions may improve communication, patient empowerment, engagement and self-management. It was discovered that patient involvement is associated with the ability to confidently cooperate and co-create caring dynamics with care providers. This is a significant finding because it establishes a link between engagement and empowerment. |

Wibe et al. also found that patients' reasons for requesting medical records included a desire for control, taking responsibility and looking for inaccuracies.[599] The themes were having a sense of control, the patient feeling co-responsible for their own health and a lack of trust in healthcare professionals to look out for their best interests. Taking responsibility gives patients a sense of control and examining accuracy may lead to the discovery of some errors which can be rectified. However, reading the record caused patients to feel as if they were not being taken seriously and the record stigmatised their lifestyle problems.[600] It gave them the impression that they were not valued as individuals. As indicated by two sub-themes, this sentiment arose primarily when the patients thought that healthcare providers had undervalued them, displayed their preconceptions, or had narrow a perspective on their condition. When reading the record, patients also felt that doctors had wrongly attributed certain conditions to stigmatising lifestyle problems that the patients claimed not to have or indeed prioritise.[601]

A meta-analysis of 30 studies in the UK reported that patient access was unlikely to cause harm and generally had modest benefits, especially on doctor-patient communication and increased patient satisfaction.[602] Another meta-analysis of 18 studies reported a welcome step for patient-centred care to facilitate verbal communication in a doctor-patient relationship but that simply allowing full access without further explanation or summary was insufficient for the patient's full understanding of the condition.[603] This probably relates to the language or medical terms that are unfamiliar to the patient.

---

599 Torunn Wibe and others, 'Lay People's Experiences with Reading Their Medical Record' (2011) 72 Social Science & Medicine , 1572.

600 Ibid 1572; Peter Vermeir and others, 'The Patient Perspective on the Effects of Medical Record Accessibility' (2017) 72 Acta Clinical Belgica 186; Weinert, 'Giving Doctors' Daily Progress Notes to Hospitalized Patients and Families to Improve Patient Experience'.

601 Wibe and others, 'Lay People's Experiences with Reading Their Medical Record', 1572.

602 Ross and Lin, 'The Effects of Promoting Patient Access to Medical Records: A Review', 136.

603 D'Costa, Kuhn and Fritz, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences', 3.

While a full appraisal of these studies is outside the scope of this thesis, they provided evidence that there are two perspectives on patient access – doctors and patients – who have different expectations and beliefs, and each occupy different roles that drive a successful doctor-patient relationship. Interestingly, these studies are based on self-report questionnaires which are arguably inferred from social desirability and self-perception as opposed to using more objective outcomes that concur with quantifiable benefits to support the notion of utilitarianism.

What I find striking is that these outcomes from the patient's perspective seemingly express true and experiential benefits such as improvement in patient satisfaction, control and communication and negative effects such as feeling devalued or stigmatisation for lifestyle choices. The patients self-reported and experienced desirable and undesirable outcomes which are thus 'true or experiential' benefits in which an event has occurred and been experienced. Interestingly, the harms outlined in these studies such as inappropriate information, inappropriate timing, increased confusion and potential distress are mainly generated from the doctor's perspective, which can be considered theoretical and non-experiential. There is a pattern here in which the doctors continue to decide on behalf of their patients what is best for them. While this can be considered paternalistic, we can also claim that the doctor's duty is to advocate for patients and therefore concur with the conclusions of these studies that doctors are concerned about unrestricted patient access and the possible negative effects. Another example is the benefit of a truth-seeking exercise of which patient access is an example. Unlike Kant's theory of deontology which I will unpack later, utilitarianism requires maximum positive impact but truth-seeking may deal with pain and suffering which will not produce the greatest utility.

While the evidence is not exhaustive, the utilitarian approach is guided by the calculated benefits and harms of improving patient access. I can argue two dimensions to the evidence-

based on act utilitarianism and rule utilitarianism. In rule utilitarianism, no prediction or calculation of benefits or harms is performed to mandate an action, as decisions are guided by pre-formed rules based on evidence.[604] This concept is applied daily in everyday clinical practice and likely influences evidence-based medicine in which clinical practice is performed to produce positive outcomes based on scientific proof. The act to maximise benefits for medical records must consider that this pre-formed rule is already mandated in legislation and guidelines in many countries, and there is some empirical evidence to support the benefits as discussed earlier. The rule utilitarian states that a specific action is morally justified if it conforms to a justified moral rule, in this case respect for autonomy.[605] However, I can also apply act utilitarianism here, which deals with decisions taken for each individual to promote more benefits without examining the evidence. The evidence is limited and inferred from the perspectives of doctors and patients with clear overall 'experiential' benefits for patients. Therefore, both rule and act utilitarianism can be applied to justify wider patient access.

Decisions are made based on a result that will determine the greatest amount of benefit for the greatest number of people under utilitarianism, thus, an intervention's morality is defined by the effects of that action. In this chapter, I propose that if we embrace the utilitarian perspective based on evidence and also pre-formed rules to respect patient's autonomy, wider access for patients competent to play a role in decision-making who request their medical records, should lead to the act of accessing their medical records as we can predict overall benefits as reported in the literature such as facilitating communication, improving understanding, breaking the barrier between the doctor/patient relationship, feeling more in control of healthcare decisions and identifying errors and inaccuracies in the record.[606] The experiential benefits reported by

604 *Act and Rule Utilitarianism*.
605 Ibid.
606 Tom Delbanco and others, 'Open Notes: Doctors and Patients Signing On' (2010) 153 Annals of Intern Medicine 121; Fossa, Bell and DesRoches, 'Opennotes and Shared Decision Making: A Growing Practice in Clinical Transparency and How It Can Support Patient-Centered Care', 123.

patients are stronger than the inferential negative outcomes, or harms, contemplated by their physician counterparts and therefore, justify wider patient access. However, one limitation of this approach is that the action of accessing medical records for patients might cause little benefit or even harm to certain individuals, but no action could potentially cause the same effects. For example, a systemic analysis of electronic patient portals[607] looking at health outcomes and patient satisfaction revealed that patient race and ethnicity, education level and literacy may influence use and can create gaps in health outcomes for a disadvantaged group. This might comprise a significant percentage of the population in a certain area and therefore generate no overall benefits.[608] As importantly, given the negative effects of wider patient access as derived from the doctor's perspective including some self-experiential concerns such as a change in the practice of documentation, more time is required to explain to patients the content in the medical records and liability issues. However, these concerns raised by doctors in respect of wider access can be addressed with adequate resources and training as well as increasing capacity in healthcare communication.

### 6.2.2 Kant's deontology in widening patient access: is restricting access or non-widening access immoral?

In the previous section, I discussed the utilitarian theory to justify wider access for patients to their own medical records. However, the problem with this ethical theory is that it requires the prediction of consequences using at least some form of empirical evidence or pre-formed rules that predict maximum benefits. While there is an argument to justify wider access using the utilitarian theory, the evidence to support the benefits of this action is limited. Meanwhile the positive and negative outcomes reported in the studies lack external validation as well as using

[607] Caroline Lubick Goldzweig and others, 'Electronic Patient Portals: Evidence on Health Outcomes, Satisfaction, Efficiency, and Attitudes' (2013) 159 Annals of Internal Medicine 677, 685.
[608] Ibid 685.

experiential emotions and perceived benefits or non-experiential harms from both the patients' and doctors' perspectives respectively.

In my opinion, Kant's deontological theory provides a supplementary support to utilitarianism, to justify wider access although deontological approaches are usually described as being opposite to, or in conflict with, utilitarian or consequentialist theory. Unlike consequentialist theory, which focuses on outcome, deontology focuses on ethics where the morality of an action depends on its nature, irrespective of its consequences.[609] Here I attempt to determine whether the action of restricting or non-widening patient access following a patient request is ever justified.

In respect of wider patient access, this theory hypothesises that the 'right' thing to do is to allow patients to have access to their own information in medical records which must be prioritised as 'good'. Therefore, restricting patient access is considered 'wrong'. This theory also emphasises the element of autonomy which is part of the moral obligation for a certain action. Allowing automatic access to medical records when a patient requests it is always the 'right' thing to do. The essence of the argument to access medical records relates to the information contained within these records and this includes information on the patients themselves. The Council of Europe Oviedo Convention on Human Rights and Biomedicine (1997), Article 10(2) states that:

> Everyone is entitled to know any information collected about his health. However, the wishes of an individual not to be so informed shall be observed.

The patient's right to information can be framed as an important element of the doctor's obligation to their patient, as part of acting for the patient's benefit and respecting their autonomy as stated in the Hippocratic Oath.[610] Therefore, withholding information from a

609 Mandal, Ponnambath and Parija, 'Utilitarian and Deontological Ethics in Medicine'.

610 *Regina v Mid Glamorgan Family Health Services Authority, Ex Parte Martin* .

competent patient, especially in relation to the patient themselves, is morally unjustified and infringes on the patient's right to information and autonomy.

Patient access to medical records is an act of or exercise in truth-seeking and can be considered an act of accessing the truth about oneself because truth-telling in a clinical consultation is 'an act of sharing one's knowledge and the limitations of one's knowledge with accuracy and with sensitivity to the clinical impact of the disclosure'.[611] Truth-telling is part of a doctor's duty to be transparent and honest in the delivery of information. Sullivan, Menapace and White[612] defied the speculation among physicians that most patients do not want to hear the truth. The vast majority of patient participants said they did want to know the truth about their health and that doctors had a duty to be honest with them, particularly when they were diagnosed with a life-threatening illness.[613] Wibe et al. discovered that a lack of openness makes patients feel resentful and that distrust is a strong motivator for patients to request access to medical records.[614] Access to medical records can be a component of an exercise to seek the truth; consequently, refusing a patient's request to see their records if they choose to do so is morally wrong. As a truth-seeking exercise, deontological theory maintains that the action of automatic granting of a patient's request for access is morally good and withholding the truth is ethically unacceptable. Kant believed that lying could never be justified and that telling the truth is always a duty of a moral person, regardless if it infringes on others' right not to know or results in innocent people being severely harmed, which he claimed as an accident (see Chapter 5).[615]

---

611 Laura Weiss Roberts and Allen R Dyer, 'Confidentiality and Truth Telling' (2003) 1 The Journal of Lifelong Learning in Psychiatry 445, 449.

612 Robert Sullivan, Lawrence W W Menapace and Royce M White, 'Truth-Telling and Patient Diagnoses' (2001) 27 Journal of Medical Ethics 192, 192.

613 Ibid 192.

614 Wibe and others, 'Lay People's Experiences with Reading Their Medical Record', 1572.

615 Yusrita Zolkefli, 'The Ethics of Truth-Telling in Health-Care Settings' (2018) 25 Malaysian Journal of Medical Sciences , 136.

According to this theory, medical records should be an accurate and truthful account of a consultation and withholding this truth must be considered immoral.

There are implications for wider access as the doctor's autonomy is eroded as the creation and content of medical records can be considered their intellectual property according to the MMC.[616] According to deontology, consequences such as this should never matter and as a rights-based theory, the 'good' should always prevail. However, the practice of truth-seeking and truth-telling in healthcare is complicated as doctors deal with individuals, usually at their most vulnerable, with potentially undesirable effects. While deontology proponents claim that the consequence should not matter, the limitation of this theory is that it does not address a conflict that may arise between two moral individuals, in this case, the doctor and patient. While this theory is inadequate to support and facilitate the real-time and real-life dynamics of a complex doctor-patient relationship, it provides support to the overall discussion that restricting access is not ethically justifiable which sufficiently address the second question of the chapter (see Section 6.2).

### 6.2.3 Arguments for and against widening patient access using principlism

This section focuses on the ethical arguments for widening patient access in Malaysian healthcare using principlism. It examines whether the principlism framework developed by Beauchamp and Childress of autonomy, beneficence and non-maleficence can be used to justify wider access to medical records. I have excluded the fourth principle of justice as the issue under consideration falls predominantly under the first three. Justice mainly focuses on the distribution and allocation of healthcare resources that are not central components of this issue. It illustrates the factors influencing the arguments in favour of improving access to

[616] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.12.

medical records: autonomy and beneficence to consider justifications for wider access and non-maleficence to counterbalance arguments.

#### 6.2.3.1 Autonomy, beneficence and widening patient access

First, I discuss the principle of autonomy and how it justifies wider patient access. It is important to emphasise that healthcare undergoes constant change and this includes more patient involvement in clinical decision-making.[617] Using the discussion of informed consent in the previous chapter as the benchmark for legalising a method of information transmission that fulfils the principle of respect for autonomy as an ethical obligation, I will translate key points from that analysis to support wider patient access.

As noted in Chapter 4, information transmission and communication come in many forms. For example, informed consent allows patients to be informed about the risks, benefits and alternatives of a given procedure or intervention.[618] However, the ethical basis for patient access is that it allows patients to be informed of the information in their medical records which helps to enhance communication whilst improving better understanding of their health condition.[619] The patient must be deemed competent to make a voluntary decision to go ahead with treatment. This is where informed consent is an essential part of this circuit. The moral and legal obligation for widening patient access depends on the relevant and meaningful information that different patients require to make a clinical decision. Therefore, if the patient has a 'demand' for more information through access to their medical records, automatic granting is ethically justified, bearing in mind that not all patients' needs are the same. Relevant comprehensible information is required for autonomy, but further information beyond

617 Shea, 'Principlism's Balancing Act: Why the Principles of Biomedical Ethics Need a Theory of the Good', 463.
618 Shah and others, *Informed Consent*.
619 Ferreira and others, 'Why Facilitate Patient Access to Medical Records', 86.

relevance and understanding may enhance autonomy. The opponents of access to medical records may claim that doctors are sufficient as information providers, but the ability to receive and process further knowledge contained in medical records empowers patients and enhances autonomous decisions. Thus, the right to autonomy is protected through the right to be informed using all viable means by which information is discoverable. In allowing access to medical records, the patient is granted the background information that fashioned the decision for the procedure or treatment option that generated the need for informed consent.

Filtered or considered information has long been practised in the doctor-patient relationship and yet the importance of autonomous decision-making relies heavily on full understanding using unobtrusive comprehensive knowledge.[620] An example in clinical practice is the end-of-life situation where the patient was not informed of the median survival in absolute terms as the doctor perceived this as futile. The information in the medical records might enable the patient to understand their disease, come to terms with their condition and afford them the chance to put their affairs in order. There is evidence that widening patient access to medical records has improved the doctor-patient interaction and given individuals a better understanding of their illnesses.[621]

In having the option to access medical records as a different type of communication, clinical decision-making may become realistically achievable to maintain a good quality of life or quality end-of-life but not to the extent of over-treating an incurable condition. In a way, it provides insights to patients on the treatment outcomes, hence acknowledging the illness as realistically as possible. It helps the patient to approach their care by providing a much better understanding of their own illness and to have the capacity to appreciate and realise their medical condition and the benefits and risks of certain treatments. Complex information might

620 Edwin, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege - Is It Ever Justified?', 158.
621 Ferreira and others, 'Why Facilitate Patient Access to Medical Records', 86.

be too difficult to process in a 15-minute consultation and therefore medical records, usually reflecting a real-time account of this consultation, provide another platform for patients to revisit and digest or process the information more carefully.

Another dimension is the link between informed consent and medical records and the arguments for legal and ethical necessity that motivate the process of informed consent. While the Malaysian courts state that patients have an 'innominate right of access to medical records',[622] there has been no discussion directly relating this matter to informed consent. Taking a cue from countries such as Germany, there is a statement connecting these two subjects. According to some courts:

> The right of access to medical records derives from the patient's right not only to a diagnosis and therapy, but to information concerning their medical records, which may be related to their current state of health and future prognosis. This is in addition to the right to autonomy or self-determination, which apart from informed consent, involves an informational right of access to medical records.[623]

In Malaysia, there seems to be an inconsistent approach in Malaysian law in matters of patient access to medical records. Although there is no direct correlation between informed consent and access to medical records in Malaysia, there is a strong connection between the two especially in fulfilling the ethical obligation to respect the patient's autonomy. Therefore, as Malaysian law recognises the importance of valid informed consent as the cornerstone of respecting patient autonomy and both patient access and informed consent are about information transmission, it is not inconceivable to apply the same values already ingrained in the legal system to patient access. The fundamental argument is similar: patients are expected to be informed about their condition in ways which they can fully or almost fully understand, especially with the gradual erosion of the notion that 'doctor knows best' and the increasing

---

622 *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

623 Anatoliy A Lytvynenko, 'A Right of Access to Medical Records: The Contemporary Case Law of the European Court of Human Rights and the Jurisprudence of Germany' (2020) 6 Athens Journal of Law 103, 109.

recognition of patient-centred care. [624] This has shifted the standards which underpin important legal developments such as the recognition of human rights and respect for patient autonomy. As we shall see in Chapter 7, patient access to medical records should become a statutory right as legal necessity is entrenched and driven by ethical necessity.

Patient empowerment is an important theme in fulfilling the principlism obligation to respect patients' autonomy and beneficence. Empowerment provides room for patients to choose freely using information that is received in which the patient retains autonomy and responsibility for decision-making. Patient access to medical records is an important tool to empower patients as the ability to possess and access one's healthcare information facilitates better understanding and interest in one's healthcare.[625] Patient autonomy therefore creates positive outcomes that support patient empowerment which are inextricably linked to the principle of beneficence.

Munier and Boaden state that 'health records are seen as facilitators of the patient empowerment process as they can provide them with their medical information in its entirety'.[626] The importance of respecting patient autonomy and independent choices is because patients have unique preferences and beliefs when it comes to their own well-being. The information obtained by patients in medical records relates to an aspect of their health that they deem more significant and therefore empowers them to make the right decisions. Therefore, patient empowerment should be one of the drivers in improving autonomy, control, and involvement in benefits.[627]

---

[624] Lee, ''*Bolam*' to '*Montgomery'* Is Result of Evolutionary Change of Medical Practice Towards Patient-Centred Care'.

[625] Maryam Hannah Daud and others, 'The Empower-Sustain E-Health Intervention to Improve Patient Activation and Self-Management Behaviours among Individuals with Metabolic Syndrome in Primary Care: Study Protocol for a Pilot Randomised Controlled Trial' (2020) 21 BMC Open , 13.

[626] Samina Munir and Ruth Boaden, 'Patient Empowerment and the Electronic Health Record' (2001) 84 Studies in Health Technology and Informatics 663, 663-665.

[627] Zoish Daruwalla and others, 'Patient Empowerment: The Role of Technology' (2019) 257 Studies in Health Technology and Informatics 70, 70.

The benefits of patient empowerment are supported with evidence. In a Malaysian study, Ng et al. report that patient education is a critical step in encouraging patients to participate in decision-making. They examined the state of patient engagement in Malaysia and found access to accurate, relevant, and readable health information improves health literacy and encourages patients to participate in SDM.[628] Medical records provide health information that is unique to the patient and therefore can be a major source of useful information for the patient. A study by Wakefield et al., [629] reported a systemic review on patient empowerment in patients with critical illness, identified themes such as self-identity, personalised knowledge in theory and practice, negotiation of personal and healthcare relationships, acknowledgement of terminal illness and navigating continuous loss. The key outcome expected with improved patient empowerment was to enhance patients' 'feelings of control over their illness'.[630] However, the review reported that patients placed:

> … stronger emphasis on the benefits of equitable therapeutic relationship with healthcare professionals with respect to self-identity (feeling respected and valued) rather than focussing on the product of that relationship being to enhance their 'feelings of control'.[631]

I use this interesting study because it clearly illustrates that, in terminal illness, the unique narrative of a patient – their 'personalised knowledge', 'personal and healthcare relationship' and 'self-identity' – all pertain to the private experience that the patients may relate to in their medical records.

Another theme that relates to a patient's right to autonomy and fulfils the principles of beneficence is effective communication. There are different types of communication including

---

[628] Chirk Jenn Ng and others, 'An Overview of Patient Involvement in Healthcare Decision-Making: A Situational Analysis of the Malaysian Context' (2013) 13 BMC Health Services Research 1, 4.
[629] Dominique Wakefield and others, 'Patient Empowerment, What Does It Mean for Adults in the Advanced Stages of a Life-Limiting Illness: A Systematic Review Using Critical Interpretive Synthesis' (2018) 32 Palliative Medicine 1288, 1298.
[630] Ibid 1298.
[631] Ibid 1298.

verbal and non-verbal. Patient access to medical records can improve understanding of patient health and communication with their healthcare providers.[632] It encourages patients to be more interested and to delve into the clues which shaped the subsequent management choices, making the patient better informed. Good communication also improves patient knowledge and trust towards their doctors.[633] Medical records can serve as an impartial tool for communication in a doctor-patient relationship.

For example, information in medical records plays a role in allowing patients to fully realise and understand the condition they are in. Evidence has shown that doctors tend to communicate by being selective to steer patients towards the decision doctors deem most appropriate.[634] Patients making autonomous decisions depend very much on how doctors communicate with them, be it verbally or by the information in the form of medical records.[635] A doctor's approach to communication is guided by information that the doctor would like to obtain from the patient and structured according to the best likelihood to successfully influence the patient. Information in medical records tends to be unfiltered as opposed to carefully constructed with verbal and non-verbal diplomacy and might change the patient's decision. However, it may concur and confirm a difficult decision for patients as communication via medical records is usually in accordance with the doctor's thoughts and not an unbiased record. Therefore, medical records are also a useful reference for the patient to recount their experience in a consultation and allow any confusion or unmet needs to be addressed.

Medical records allow patients to access not just information, but the process of information and the logical conclusion to which the doctor has arrived to offer the plan of care. The doctor's

---

632 Ross and Lin, 'The Effects of Promoting Patient Access to Medical Records: A Review', 132.

633 D'Costa, Kuhn and Fritz, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences', 17.

634 Ghosh, Josh and Ghosh, 'Effective Patient-Physician Communication – a Concise Review' .

635 Laura A Brooks, Elizabeth Manias and Melissa J Bloomer, 'Culturally Sensitive Communication in Healthcare: A Concept Analysis' (2019) 26 Australian College of Nursing 383, 384.

professional thought process is usually standardised to include a background of presenting complaint, medical history, medications, social history, differential diagnosis, a clinical impression of a working diagnosis and the plan of care. The history dictated in the medical records gives a clue as to which are the important aspects and shaped the thought process into a particular management decision. Allowing access to medical records allows an understanding of how this thought process and management option came about and a realisation that it is a carefully deliberated choice rather than a quick action. Another example is of a patient with a recent cancer diagnosis that is almost always discussed in a multidisciplinary meeting including physicians, surgeons, and medical and radiation oncologists and is subsequently recorded in the medical records. The patient would likely be more assured that deliberation and discussions have taken place with several experts in their fields within a specialised cancer network and this process could influence a patient's decision to accept the offer of treatment. It is also easier to accept the decision in a frail patient for whom the multidisciplinary team has decided against administering systemic treatment such as chemotherapy as this could do more harm.

Studies have shown the suggested benefits of patient access. Vermier et al. identified the majority (patients) had a positive experience, generally experiencing less anxiety and feeling reassured with improved communication with their physician'.[636] One study identified that communication of written information was considered superior to verbal explanations.[637] Communication through access to a portal was also examined. A Patient Clinical Information System was created to resolve issues relating to access to medical records by the patients themselves.[638] The system produced beneficial effects on health outcomes through the shared

[636] Vermeir and others, 'The Patient Perspective on the Effects of Medical Record Accessibility', 189.

[637] Lauren Wilcox and others, 'Designing Patient-Centric Information Displays for Hospitals' (Proceedings of the SIGCHI Conference on Human Factors in Computing Systems).

[638] Refer to James J Cimino, Vimla L Patel and Andre W Kushniruk, 'The Patient Clinical Information System (Patcis): Technical Solutions for and Experience with Giving Patients Access to Their Electronic Medical Records' (2002) 68 International Journal of Medical Informatics 113.

workload of doctors and patients resulting in better communication and negotiation. Another study looked at the use of electronic portal access and claimed that patients believed the portal would facilitate face-to-face communication rather than replace it. The portal must be easy to use and 'familiar'; this was considered particularly important for the acutely unwell patient.[639]

A systematic review study also confirmed that patient access facilitates verbal communication that takes place in a consultation.[640] Shenkin and Warner looked at both positive and negative outcomes in patient access, especially on effective communication. The advantages include facilitating patient education concerning their own health, reducing the credibility gap between doctors and patients and allowing open access and better transparency which might deter malpractice litigation and improving patient compliance and communication.[641] Altman reported that some patients tend to be reassured by reading their medical records which place more confidence in the treatment offered by their doctors.[642]

Effective communication can also include the option of direct access to medical records for patients if they desire non-verbal communication or if requiring more comprehensive information on their health. This option to be given automatic access to medical records may not be an absolute necessity for all patients but would certainly empower patients with further options on their response to doctors and extra information gleaned from medical records may complement their understanding and meaningful communication with doctors. In this instance, communication includes the ability to facilitate an accurate diagnosis, for instance, provide

639 Sarah A Collins and others, 'Acute Care Patient Portals: A Qualitative Study of Stakeholder Perspectives on Current Practices' (2017) 24 Journal of the American Medical Informatics Association 9, 14.
640 D'Costa, Kuhn and Fritz, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences'.
641 Budd N Shenkin and David C Warner, 'Giving the Patient His Medical Record: A Proposal to Improve the System' (1973) 289 New England Journal of Medicine 688.
642 John H Altman and others, 'Patients Who Read Their Hospital Charts' (1980) 302 New England Journal of Medicine 169, 170.

proper counselling or therapeutic instructions and build compassionate relationships with patients.[643]

In this section, I used principles of autonomy and beneficence as they relate to the principlism theory to justify wider patient access using medical records as a tool for further information transmission in a doctor-patient relationship. I used concepts previously applied to the process of informed consent, patient empowerment and effective communication as the basis of medical ethics in fulfilling the obligation 1) to respect the patient's autonomy and 2) to benefit them. These key concepts in everyday practice act as an analogy for the cause and effects of wider patient access. There is an ethical imperative and even a necessity that mandates a change in practice which should form the basis for legal reform.

#### 6.2.3.2 Non-maleficence and widening patient access from the doctors' perspectives

Thus far, the main resistance to wider access is from the healthcare providers themselves. Wider access using the ethical framework of principlism in which the doctor's perspective places a stronger emphasis on non-maleficence can also be justified.

Baumgarten notes that 'the notion that patients have a moral claim to direct the course of their own medical care and to be given reasonably full information to make medical decisions is the most significant challenge of the bioethics movement to conventional medicine'.[644] This is because individual freedom and patient autonomy are complicated by the competing concerns of the doctors' professional autonomy to act in the best interest of the patient. As the two may conflict, this section uses the principle of non-maleficence to consider the argument that 'doing the right thing' and granting wider access to medical records might precipitate unintended consequences and create moral and social conflicts between doctors and patients. This section

[643] Fong Ha and Longnecker, 'Doctor-Patient Communication: A Review', 40.
[644] Baumgarten, 'The Concept of Patient Autonomy', 1. Baumgarten, "The Concept of Patient Autonomy," 1.

explores the complexity of engaging principlism, a balancing act in which autonomy and beneficence favour patient access while non-maleficence is the counterbalancing argument from the doctors.

Here I introduce the doctor's role in a clinical system of communication, one in which a reasonable doctor is acting in the patient's perceived best interest using communication to relay their expertise to the patient to make informed decisions. This is important as doctors occupy a role in the medical system through communication[645] which gives meaning to their social interactions and the power to differentiate or exclude other types of information outside the scope of a consultation. For example, religious and cultural inclusion is not necessarily an integral part of a consultation. However, in this clinical system of communication, information that the doctors can supposedly exclude or differentiate is not straightforward as what is considered relevant differs between individuals. This system of communication creates an ethical dilemma when the patient agrees or disagrees with treatment based on the communication provided by doctors. Thus, medical records that are made readily accessible to patients can improve medical care by enhancing doctor-patient communication as this gives another layer to the system of communication. It enables patients to have an extra source to better understand their condition and treatment and feel more in control of their health[646] by understanding the health clues, results and the thinking process that can be obtained from medical records. It can also give rise to concerns that routinely giving patients access to written documents which are not intended for, or easily understood by, the layperson can cause misinterpretation or contain information that is inappropriate to divulge.[647]

---

645 Horton, 'Accountability and Time', 131.

646 Agency for Healthcare Research and Quality, 'Strategy 6h:Tools to Help Patients Communicate Their Needs' (2013) <www.ahrq.gov/cahps/quality-improvement/improvement-guide/6-strategies-for-improving/communication/strategy6htools.html>, accessed 6 January 2021.

647 Ross and Lin, 'The Effects of Promoting Patient Access to Medical Records: A Review', 130

Medical records were not created for the non-professionals but are clinical and legal documents created by health professionals for health professionals. Patient access can be for several reasons (see Chapter 2) but the majority of Malaysian patients request access to medical records for litigation and not necessarily to seek further knowledge. Another point to note is that medical or scientific terminology in medical records does not guarantee the patient's right to information that leads to an autonomous decision as the patient's level of understanding could never match that of a doctor who has undergone many years of medical training. The stressful event of being a patient itself and the bias caused by physical and emotional distress may affect the perception and experience of accessing medical notes, especially without the facilitated communication that is routinely provided by the doctor. Hence, communication through the process of allowing patient access directly without a mediator such as the healthcare provider could be problematic as, without appropriate guidance, patients may have difficulty understanding their records and interpreting them appropriately.[648] The content in medical records is often objective and insensitive. Adding to this confusion is the counterintuitive practice of doctors in writing information that is professionally authoritative and that may not reflect a practice that preserves the patient's autonomy.

There is a lack of discussion on the topic of medical records on what is considered inappropriate content or information for patients. For example, sexual content or 'offensive language' on television is considered inappropriate for younger children because they could not process the information and how this information is staged due to a lack of maturity and knowledge. While we can argue that the level of content in medical records would not be processed in the same manner by patients as it was created by healthcare professionals for healthcare professionals and that it might cause stress, anxiety and confusion, the information remains truthful but the way it is documented may influence interpretation by the patient. The language of the

[648] Ibid 136.

information and how this is presented can often be difficult for patients to directly process on their own. There is also inappropriateness in time and space, in which information is not delivered sensitively. For example, having real-time access to medical records might disclose a diagnosis of cancer while the patient is alone without the family or support structure as well as their physician who usually facilitates the delivery of information to provide much-needed reassurance in an appropriate time and space.

As doctors are concerned that access to medical notes might overwhelm or unnecessarily worry patients, Grossman et al. also suggest that it 'may be prudent to omit or explain potentially alarming information that carries a low degree of certainty such as a cancer'[649] so that the doctor is available to offer support and interpretation.[650] Wider access to medical records would mean the loss of the opportunity to be appropriately receptive as breaking bad news is usually performed by a good doctor using an appropriate place, time and language and with considerable sensitivity. In a consultation, the doctor must take reasonable care to inform the patient of 'material risk' or undesirable information but this does not happen if the patient read the information directly from their medical records.

In Malaysia, doctors and hospital providers are the owners of medical records. They have the power to decide whether certain information like that collected from third parties and the opinions of doctors based on test findings can be disclosed. However, rather than having a physical copy of the patient record, patients are permitted to have information regarding illnesses, treatments and medications supplied to them in medical reports. The information in the medical records is the patient's but is written by and belongs to the doctors and hospitals who control what information should be provided. Therefore, although the information may be

[649] Lisa v Grossman and others, 'Implementation of Acute Care Patient Portals: Recommendations on Utility and Use from Six Early Adopters' (2018) 25 Journal of the Americal Medical Informatics Association 370, 376.
[650] Krzysztof Sobczak, Katarzyna Leoniuk and Agata Janaszczyk, 'Delivering Bad News: Patient's Perspective' (2018) 12 Patient Preference and Adherance 2397, 2403.

undisputed facts regarding the patient, the way that information is documented in writing, language, the nuance of orders and prioritisation as well as the confounding effects such as the patient's current physical and emotional status play a role in the interpretation of the medical records, be it undisputed information or thought process and management. Widening access to medical records for patients may do more harm than good, hence causing maleficence. The principle of non-maleficence can be considered as 'doing the right thing', hence widening access to medical records might have unintended consequences and create moral and social conflicts between doctors and patients.

Another delicate consideration is to allow the patient to make autonomous decisions that align with their values and wishes. However, in a vulnerable position in which patients may be in emotional turmoil, their decision to accept or refuse treatment might be perceived as autonomous but in reality, does not encompass their hopes and expectations. For example, the patient may reluctantly choose a treatment pushed by the doctor as the best choice, but which the patient knows might cause further anxiety and stress in the future.

Another dimension to the non-maleficence reason to restrict wider access is that providing more information might also forward the responsibility of clinical decision-making to the patients themselves. '[I]n the so-called co-operative mode, guidance dominates to the point where most patients, realistically and appropriately, want the doctor to take responsibility for their health'.[651] In other words, the doctor may shift the patient's choice to delegate responsibility or worry to their patients by providing them with more information. For example, a doctor initiates communication by providing medical records concerning the ceiling of care for a patient with advanced organ failure due to the futility of treating their disease. To respect their autonomy, the doctor provides sensitive information in the records which require the

[651] D'Costa, Kuhn and Fritz, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences', 17.

patient to make an autonomous decision on whether to resuscitate or not. The patient is overwhelmed, causing mental distress and affecting decision-making.

One of the reasons why I use medical paternalism and therapeutic privilege as a way of conceptually understanding the practice through a doctor's lens is due to the perceived threat of harm from too much information[652]. Despite the increasing acknowledgement of the patient's autonomy, I suspect this is one of the most compelling reasons why medical paternalism and therapeutic privilege continue to exist and be endorsed, both professionally and legally. In exercising respect for patient autonomy and practices that favour disclosure and yet are inextricably linked to non-maleficence, there may be a need to use the paternalistic approach and limit access to information, including medical records.[653] To date, there are no universal guidelines on 'harm' or 'perceived harm' to help doctors define when it may be justifiable to exercise the balancing act between respecting autonomy and medical paternalism.

Some courts recognise therapeutic privilege to promote non-maleficence. For example, in *Cantenbury v Spence*,[654] the Court decided that a practitioner is not obligated to disclose when disclosure would risk harm to the patient. The physician may withhold such information from the patient or filter the information in such a manner that is sensitive to the patient, which is not usual in medical records.[655] The US case of *Cobbs v Grant*[656] stated that doctors who are expert in their knowledge and skill feared that patient lack of skill would create unnecessary fears and hopes and jeopardise the doctor's skill and role to advise. The Court, therefore, endorsed therapeutic privilege and found that the doctor has available certain defences which

---

652 Oliver Quick, 'Outing Medical Errors: Questions of Trust and Responsibility' (2006) 14 Medical Law Review 22.

653 Dermot Feenan, 'Medical Records: Law, Paternalism and Harm' (1995) 29 Journal of the Royal College of Physicians of London 401, 107.

654 American Medical Association, 'Records of Physician: Information and Patients' (2011), accessed 7 June 2021.

655 Ibid.

656 *Cobbs v Grant* [1972] 8 Cal 3d 229.

may justify a failure to disclose including keeping the information from the patient if the patient so requests.[657]

However, the UK court did not recognise therapeutic privilege in *Montgomery*.[658] The term 'therapeutic exception' was used to imply a defence to a claim for non-disclosure rather than an aspect of the duty of disclosure, in which this limited exception must not be abused. The difference between these two countries illustrates the tension between respecting a patient's autonomy and protecting a patient from harm, especially in relation to information. This could also extend to the information contained in medical records. The practices of therapeutic privilege and exception, if applied to medical records, must place a stronger emphasis on the fact that the information processed by patients could be immaterial, unnecessary, and irrelevant for the patient and therefore widening access is not necessarily purposeful nor of any further benefit for patients and could produce negative effects. As the MMC Confidentiality Guidelines state a practitioner may not improperly disclose information which he obtained in confidence about a patient,[659] the doctor may avoid liability for failure to warn of a material risk if he can show that he reasonably believed that communication to the patient of the existence of the risk would be detrimental to the health including the mental health of his patient.

In summary, I have illustrated the ethical argument against wider access to medical records using the principle of non-maleficence from the doctor's perspective, with themes such as the system of communication including medical paternalism and therapeutic privilege which argue against wider patient access.

---

657 Ibid.

658 Refer to *Montgomery v Lanarkshire Health Board* [85], [91].

659 Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Confidentiality*, cl 1.

Thus far, I have presented the arguments for and against wider patient access primarily from the viewpoint of three competing principles: autonomy, beneficence and non-maleficence. The individual principle fits either into the category of for or against a conflict between the three.

## 6.3 Analysis

In this chapter, I have considered the arguments for and against wider patient access drawing on utilitarian, deontological and principlist approaches. Using the utilitarian approach which proposes that the right thing to do is the one that leads to the most beneficial consequences, I outlined empirical evidence to suggest that the benefits from wider patient access mainly stem from the patient's perspective, which is not surprising as the proponents of access claim that this practice promotes respect for patient autonomy and therefore benefit patients the most. Deontological proponents claim that if access to medical records is considered a truth-seeking exercise, then the act of restricting patient access should always be considered immoral, despite the consequences. These concepts bolster my justifications for widening patient access despite it being separated from the principlist theoretical enquiry.

I used principlism and the concepts around common but important themes in everyday medical practice such as informed consent and therapeutic privilege to explore how the competing interests between the principlist principles of autonomy, beneficence and non-maleficence argue for and against wider patient access. However, these ethical theories have strengths and limitations (see Chapter 5) and therefore this chapter does not attempt to address whether widening access is the 'right' thing to do although the aim is to bring the tensions between the different principles to the surface, as doing so contributes to understanding how and why in making the necessary legal and regulatory reforms. This should help us address the unique situation in Malaysia whereby patient access is routinely obtained via a court order.

The conflicting interests of the principles of respect for autonomy and beneficence vs. non-maleficence in which one principle should not always take precedence over another provides a challenging debate for the stakeholders of the current healthcare system in the issue of wider access to medical records. Despite the competing concerns championed by each principle, some authors argue that 'modern health autonomy is considered an obligation equivalent to, or even more compelling than the principle of beneficence and non-maleficence'.[660] 'Truth' is another important element discussed in the deontology section, to which the principles of respect for autonomy are linked. The moral argument in favour of truth-telling is an obligation of fidelity and the need for trust in the doctor-patient relationship. Trust is the essential quality that drives a good doctor-patient relationship[661] which could not be built on untruthfulness.

Untruthfulness or telling lies is the extreme negative end of the spectrum of doctor-patient communication. Not telling the whole truth can be linked with the exercise of therapeutic privilege or exception which I used in the principle of non-maleficence to underpin the discussion against widening patient access. While non-maleficence drives the argument for medical paternalism and therapeutic privilege, the objective of paternalism – like that of autonomy – is for the good of the same moral agent, the patient.

Edwin objects to therapeutic privilege as closing off opportunities for SDM[662] and claims that therapeutic privilege has no place 'since information is a powerful tool for both harm and good, consciously withholding information from competent patients disempowers them and requires greater justification than patient welfare'.[663] Although Edwin wrote this in the context of the failure to inform of serious risks in procedures, he also argued that withholding information

---

660 Lucija Murgic and others, 'Paternalism and Autonomy: Views of Patients and Providers in a Transitional (Post-Communist) Country' (2015) 16 BMC Medical Ethics 1, 7.

661 Gordon Stirrat and R Gill, 'Autonomy in Medical Ethics after O'neill' (2005) 31 Journal in Medical Ethics 127, 128.

662 Edwin, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege - Is It Ever Justified?'.

663 Ibid 156.

from competent patients does not benefit them in the long term and can cause more harm than good, in addition to disregarding their autonomy. Undesirable information is part of life, but there is no evidence to suggest that, as a human being affected by unwelcome news, a patient's capacity to make decisions is necessarily impaired. It is the central tenet of a patient's right to self-determination whether to make a decision based on 'irrational reasons' or no 'reasons' at all'.[664] Emily Jackson uses insights into behavioural economics to question the court's view of patients as consumers who need information to make sound treatment decisions.[665]

Drawing on these key concepts to see how access to medical records can be appropriately configured, I have argued that withholding information on one's own health and the 'perceived' harm caused by another party creates a tension between important ethical principles. However, the argument against wider patient access based on withholding information framed as therapeutic privilege for non-maleficence is legally endorsed in some jurisdictions [666] and widely practised including in Malaysia, these questions that I have adapted from Cave[667] require further validation to fully approve therapeutic privilege under the lens of ethics:

1. If therapeutic privilege was allowed to persist to fulfil the principle of non-maleficence, to what standard could the physicians who invoke such practice be judged?
2. What is considered serious harm; do we count serious harm as perceived harm by the doctors or reference these harms based on the patient's perspective?
3. While there are competing sides to justify therapeutic privilege (patient's autonomy vs non-maleficence), is it really necessary? [668]

---

[664] *Sidaway v Board of Governors of the Bethlem Royal Hospital*
[665] Refer to *Montgomery v Lanarkshire Health Board* [50].
[666] *Canterbury v Spence*; *Reibl v Hughs* [1980] 2 SCR 880
[667] Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception'
[668] Ibid 146.

For the first question, the standard in which the physicians could invoke the practice of therapeutic privilege should be considered suboptimal as courts including in Malaysia have rejected the *Bolam* test for the duty to advise and must disclose material risks considered significant to the reasonable patient. Non-maleficence, or *primum non nocere*, might be the least fitting principle in medicine as medical treatment often entails potentially harmful procedures and interventions, although it depends on how we define harm and balance the risks with benefits. In many arguments on this conflict, autonomy seems to prevail over non-maleficence. Applying this concept, if a competent and autonomous patient requests access to their medical records, the content should be considered 'significant' and not immaterial and therefore should not be withheld.

To answer the second question, in consideration of widening patient access, there is little evidence to suggest that the doctor's perception of harm with wider access is 'significant' or even 'experiential'. This argument is further exacerbated by the lack of evidence that breaking bad news and undesirable information have led to patients becoming incapable of rational decision-making. Therefore 'harm', regardless of whether it is perceived or material harm, has not been proven and remains as a perception. It is thus only of theoretical relevance to the current discussion to support non-maleficence to restrict patient access to medical records.

For the third question, I argue that the answer is linked to the first two. There is evidence that, with a life-threatening disease, informing patients truthfully does not result in a higher incidence of 'harm' such as anxiety, despair, sadness, depression, insomnia or fear.[669] In fact, better communication and truth-telling in an exercise where truth is sought by the patient for whatever reason, these practices should be considered an integral part of the doctor-patient relationship, especially if trust is considered a central tenet of the relationship. I introduce this

[669] M Gold, 'Is Honesty Always the Best Policy? Ethical Aspects of Truth Telling' (2004) 34 Internal Medicine Journal 578, 579.

concept of trust as a potential solution for this issue in the next chapter, but these three lines of reasoning raise the question of whether therapeutic privilege, which drives the argument against widening patient access in this thesis, is obscured and unjustified.

## 6.4 Conclusion

In conclusion, I have used:

1. The utilitarian approach to justify wider patient access to maximise benefits using empirical evidence.
2. The deontological approach that restricting medical records is 'wrong' and therefore, Malaysia should widen patient access.
3. The principlism approach discusses the argument for and against using the patient's and doctor's perspectives.

After considering the conflict between principlism, autonomy and beneficence versus non-maleficence, I conclude that respecting patient autonomy must triumph as the central tenet in bioethics which has been rationalised in the form of informed consent.

Following Cave's reasoning, I propose that these principles are not necessarily incompatible as they do not derail the ultimate goal which is to serve the patient's best interest. Using these three questions as the platform to answer my research question, I have built up views, reasonings and justifications. The argument supports the notion that Malaysia should widen patient access. However, acknowledging the different views of doctors and patients is of paramount importance as it helps to reform and align the ethical and legal reasoning to widen patient access. The different views and understanding of how this debate interacts within this

complex regulatory space act as a temper in finalising the situation and environment, legally and ethically, in making wider patient access a reality.

# PART THREE: REGULATORY CHALLENGES AND RECOMMENDATIONS

## Chapter 7. Regulatory challenges to widening patient access

### 7.1 Introduction

In Part one, I mapped out the regulatory space in Malaysia to recommend strategies that can be adopted to improve and facilitate wider access to medical records for patients. In Part two, I discussed the important ethical elements and concepts that influence and justify widening patient access in Malaysia using the principlism framework. However, despite the general comparison to the regulation in the UK and the general application of principlism, there are particular complexities for Malaysia as an Asian country with distinct social hierarchies that persist, and in which doctors and healthcare providers continue to enjoy high social status.

This chapter aims to use the information on the current regulatory space in Malaysia in Chapter 2 and map out the regulatory challenges which would be needed if Malaysia were to allow automatic patient access to their medical records. While I have opined that widening access to patients is ethically the right thing to do, improving regulation to achieve this whilst protecting patient interests and advancing their rights must be addressed. However, I will identify certain regulatory failures that exist in the current situation to help understand why Malaysia is unique and needs a local response to this issue. I should also consider whether state-centric methods like legislation can work to provide definitive legal protection for that access. I will then go on to argue that perhaps the most sustainable and resilient method for improving wider patient access may not necessarily be by using regulatory levers and mechanisms alone, but also by encouraging behavioural change in the stakeholders involved.

## 7.2 Regulation

There has been considerable scholarship on formal state regulation. Formal rules comprise 'all the codified laws and regulations that are issued by a legislative process or formal decree'.[670] These may be promulgated at the national level or locally but are legally transcribed. Non-formal rules such as guidelines may be unwritten and are often described as 'soft laws' which are neither legally binding nor enforced. I described the formal and soft laws on patient access in Malaysia in Chapter 2. It is important to analyse the causes, practices and effects that shape the regulatory space in Malaysia before a set of recommendations can be proposed to reform the practice of patient access. These are crucial and will result in better understanding, anticipating complications and improving the implementation process.

Regulation is a contested concept with a vast scope of theory and practice. As the aim of this thesis is to provide recommendations on regulatory reform, an introduction to regulation is important. I do not intend to analyse regulation in detail but enough to understand the basic regulatory domain of patient access in Malaysia. This will allow insights into the regulatory challenges to widening patient access. As regulatory bodies work differently around the world and between jurisdictions, only the regulatory bodies relating to the domain of patient access in Malaysia will be examined.

Regulation is a complex virtual system that defines any social organisation using constant activities such as the design of general rules, the creation of institutions and the implementation and enforcement of rules.[671] Supporters see regulation as a 'technocratic device that has the potential to exert rational controls over important economic and social activities'.[672] In addition

---

[670] James T Thomson and Karen S Freudenberger, *Crafting Institutional Arrangements for Community Forestry:The Characteristics of the Rules and Resource Management Incentives* (1997). Definition in chapter five.

[671] Hancher and Moran, 'Organising Regulatory Space', 149.

[672] Baldwin, Cave and Lodge, 'Introduction', 2.

to being seen as a discrete mode of 'governmental activity',[673] regulation has also been defined in a number of ways. Selznick's definition of regulation is, 'sustained and focused control exercised by a public agency over activities that are valued by the community'.[674] Baldwin proposes four concepts: The first is a specific set of commands as substantive law (command and control) in which regulation entails the enactment of a collection of rules that must be followed by a body dedicated to this task. The second is deliberate state influence. This is where regulation takes on a broader meaning, encompassing all state measures aimed at influencing economic or social behaviour. As a result, command-based regimes and a variety of other mechanisms of influence fall under this category. The third includes all types of social and economic influence; all processes influencing behaviour, whether state-based or derived from other sources, are considered regulatory.[675] The 'smart regulation' hypothesis asserts that regulation can be carried out by a variety of bodies other than state institutions including corporations, self-regulators, professional or trade associations and non-profit organisations.[676] Finally, any activity that limits or inhibits the occurrence of certain undesirable behaviours can contribute to the regulatory process. The regulative effect might be enabling or facilitative.[677] This is usually seen as limited since it implies that regulatory laws are intended to confine rather than enable or encourage activities and because only governments regulate.[678] Thus, Baldwin has three main conceptions: (1) regulation as 'the promulgation of an authoritative set of rules, accompanied by some mechanism for monitoring and promoting compliance with

673 Robert Baldwin, Colin Scott and Christopher Hood, *A Reader on Regulation* (Oxford University Press 1998).
674 P. Selznick, *Focusing Organisational Research on Regulation* (Regulatory Policy and the Social Sciences, Univeristy of California Press 1985), 363.
675 Baldwin, Cave and Lodge, 'Introduction'.
676 Neil Gunningham and Darren Sinclair, 'Smart Regulation', *Regulatory Theory* (ANU Press 2017).
677 Baldwin, Cave and Lodge, 'Introduction'.
678 Ibid 3.

these rules';[679] (2) regulation as 'all efforts of state agencies to steer the economy';[680] and (3) regulation as 'all mechanisms of social control-including unintentional and non-state processes'.[681]

The concept of the regulatory space proposed by Hancher and Moran[682] is that regulation is best understood through the analytical process of a regulatory space and how national, political and legal settings influence the shape of that space and the allocation of power within it. Regulation is the defining element of any system of social organisation and the regulatory space is dominated by large hierarchical bodies. The allocation of power and influence within the regulatory space is affected by legal tradition and a wide range of social, economic and cultural factors. The plurality of the regulatory process and its openness to a variety of actors are themselves functions of bureaucratic and legal traditions and of past regulatory practice. Later, I will describe how these social orders exist in Malaysia, mapping the state and non-state actors involved in patient access and the regulatory challenges they face. The question is whether both state and non-state actors can spur and improve moral and behavioural attitudes in improving patient access, or whether a non-centralised approach is needed to encourage and support patients and doctors to make better choices in patient-centred care.

## 7.3 Regulatory challenges

The regulatory domain on widening patient access to medical records in Malaysia is complex and uses a mixture of regulatory tools. Malaysia can overcome these challenges but a state-

[679] Ibid 3.
[680] Ibid 3.
[681] Jacint Jordana and David Levi-Faur, 'Chapter 1 in the Politics of Regulation', *The Politics of Regulation in the Age of Governance* (Edward Elgar Publishing 2005), 2-4.
[682] Hancher and Moran, 'Organising Regulatory Space', 148.

centric nation like Malaysia may have to use methods like legislation as a means to provide definitive legal protection for this right.

Central to this are the state actors including organisations that are directly involved with the actions and rulings of governments concerning access to medical records and the regulatory bodies and actors involved in its management. The non-state actors are organisations or individuals who are not directly involved or allied to the state but can influence the actions and rulings of the state. The most sustainable and resilient method for granting and improving patient access to medical records is to not only use the state's regulatory levers and mechanisms, but also to encourage attitudinal change at the non-state level.

### 7.3.1 Decentred regulation and its role in society

The concept of 'decentred regulation' can help re-draw the Malaysian regulatory map and the idea that regulation can happen in the most unlikely of places and help identify those regulatory levers that would not otherwise be identifiable.[683] This helps explain the regulation of patient access to their medical records functions and how this 'decentring regulation' strategy helps in pushing the necessary levers required in making the changes to this practice in Malaysia.

Decentring is a phrase that encompasses a variety of concepts and has both positive and normative aspects. It is a phrase that is underpinned by the contention that, 'governments don't have a monopoly on regulation and regulation happens within and between different social actors'.[684] As regulation encompasses a wide variety of activities beyond formal state regulation, regulatory organisations' powers are simply one of them. Patients are also participants in the regulatory process as, for example, participants in clinical decisions and

[683] Julia Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 Current Legal Problems , 142.
[684] Julia Black, *Critical Reflections on Regulation* (Centre for Analysis of Risk and Regulation at the London School of Economics and Political Science 2002), 2.

policy-making with rights to voice their concerns and exercise their autonomy which in turn can influence policy and regulation.

However, Majone stated that the main actors in regulation are:

> … the agencies [...] created by democratically enacted statutes which define the agencies' legal authority and objectives; that the regulators are appointed by elected officials; that regulatory decision-making follows formal rules which often require public participation.[685]

According to Majone[686] expertise has always been a crucial source of regulatory agency and legitimisation because regulation is reliant on scientific knowledge. As a result, a regulatory agency with extensive knowledge possesses greater power than the administrator. The actor is based on enforced self-regulation of professional representative bodies which combine protecting self-interest with wider advocacy and another category is the variety of other representatives and stakeholder bodies in civil society.[687] Malaysia seems to lack public participation in professional bodies. For example, there is a lack of public participants in research ethics committees in Malaysia[688] and, unlike their counterparts in the UK, a lack of agents such as members of the public, patient advocates and legal experts in the MMC is observed.

All the main regulatory bodies have their own disciplinary committees. The MoH is the direct state regulator as it acts as an internal regulator of its own facilities and is the main regulatory actor and a major employer of health professionals and provider of healthcare services. The MMC meets the definition of a core regulatory body of the medical profession as it is provided with a legal framework and governed by the Medical Act 1971 and Medical Regulations 1974.

---

685 Giandomenico Majone, 'From the Positive of the Regulatory State: Causes and Consequences of Changes in the Mode of Governance' (1997) 17 Journal of Public Policy , 160.

686 Ibid 157.

687 Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992).

688 Sharon Kaur, 'The Adequacy of the Ethics Review Process in Malaysia: Protection of the Interests of Mentally Incapacitated Adults Who Enrol in Clinical Trials', University College London.

These are the state-sanctioned bodies with powers granted by Parliament and agents of direct government regulation. These Acts made the MMC the custodian of the medical profession. Therefore, for regulating the health sector, regulatory bodies such as the MMC are either sanctioned by the state or through direct state legislation.

Despite the MMC's powers and functions established under the Medical Act 1971, it is not a self-contained entity but rather is state-funded and its budget is managed by the MoH's Medical Division which means that it does not have its own financial resources. It is staffed by public officials who are paid by the MoH which oversees the organisation's activities. As a government agency funded by the Ministry, the MMC is assured of funding as it acts for the public interest, although it operates a different model from medical councils in other countries. For example, the General Medical Council (GMC) in the UK is funded mainly by fees imposed on doctors for their registrations.

The MMC's failure to practice patients' right to access medical records has led to restrictions which is an illustration that regulation can happen in the most unlikely of places. The MMC lacks the regulatory power to enforce its guidelines and therefore patient access to their medical records is usually obtained through a court order. Here we can attribute that unrecognised 'right' and inconsistent authority in regulating patient access as the main impediments leading to a regulatory failure. The ill-defined rights of patients remain difficult to enforce due to the practice of requiring a court order. Black used 'administrative and cultural logic'[689] as contributors to regulation and the administrative process leading to access has led to the cultural default of obtaining access through court orders instead. These administrative and cultural logics feed into other habits such as medical paternalism and the lack of autonomy that act as positive reinforcement. Therefore, the predicament arises from regulatory failure that feeds

[689] Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World'.

into a cycle of circumvention that continues to limit patients' rights and endorses the higher social order of healthcare providers.

When regulators fail to generate the outcomes specified in their mandates or do not effectively fulfil outcomes that are stipulated in the mandate, they are regarded as a failure as well.[690] For Malaysia, the core function of MMC, besides regulating the medical professionals, is to 'prescribe and promulgate good medical practice'.[691] One negative outcome that I observed with the MMC as a state-sanctioned regulatory body is ignoring the right of patients to access their medical records in good faith. It has failed to regulate the guidelines intended for medical professionals and to apply part of its guidelines and doctors are ignorant of the right as a result.

Hirschman also discussed regulatory failure, based on futility, jeopardy and perversity.[692] Futility asserts that no change to the existing situation will occur regardless of regulatory efforts. Perhaps having a clause in the MMC Guidelines of acting in good faith supports the notion of a rhetorical statement in which a state regulatory body creates and endorses access. However, it is still a hindrance as is evident from *Nurul Husna*[693] and *Nur Syarafina*[694] where access to medical records was not granted by the hospital providers and access was procured only through a court order. Therefore, the reference to morality and ethics in the MMC Guidelines seems more rhetorical, given its lack of definition of what constitutes good faith, which deems this reference as 'futile' as per Hirschman as this practice has almost no influence on patient access in Malaysia.

---

690 Refer to Baldwin, Cave and Lodge, 'Regulatory Failure'.

691 Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Good Medical Practice* .

692 Albert O Hirschman, *The Rhetoric of Reaction: Perversity, Futility, Jeopardy* (The Belknap Press of Harvard University Press 1991).

693 *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*

694 *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*

Black has also described a behavioural adjustment that takes place both within and outside of the state[695] in which individuals and organisations link up, pool resources and direct the flow of events to a specific regulatory outcome[696] results in unanticipated and unintentional effects and changes in behaviour. An act of regulation can be intentional where many participants are engaging with each other and carrying out activities that shape the regulatory environment in a certain way that is beyond the control of a single participant. This echoes the argument of neoliberal economists that absolute state or central planning and design are impossible to succeed because the entity cannot possibly possess the knowledge and experience about the finer dynamics of the domain they are attempting to regulate. Braithwaite states that regulation is about, 'steering the flow of events and behaviour, as opposed to providing and distributing'.[697] This realisation has prompted states to, as Braithwaite sees it, 'steer' rather than 'row'[698] the regulatory boat. In healthcare provision, participants like patients and their families may influence the regulatory environment in healthcare beyond the medical professionals and higher authorities. However, for Malaysia, overall regulation on access to medical records does not portray this balance of influences that can both come from the top in the form of regulatory and legal powers and from the bottom as empowered patients. It lacks dialogues on patient empowerment and the regulators themselves, such as the MMC and the MoH, despite being given the 'high persuasive authority' of the courts, have limited capacity to act effectively in this matter. The practice among medical professionals and hospitals to refuse copies of patients' medical records unless so ordered by the court, in addition to portraying the MMC as a regulator, is perhaps aggravated by 'political unwillingness'[699] to

695 Black, *Critical Reflections on Regulation*, 1.
696 John Braithwaite, 'Neoliberalism or Regulatory Capitalism?', *Regulatory Capitalism: How It Works, Ideas for Making It Work Better* (Edward Elgar 2008)
697 Ibid 1.
698 Ibid.
699 Baldwin, Cave and Lodge, 'Regulatory Failure', 71.

contemplate legal adjustments. According to Grissinger, people like doctors will not always change their methods regardless of regulatory participation, especially if they are in higher positions in the chain of command: '[t]he hierarchical nature of healthcare and a sense of privilege and status can lead those at the top of a hierarchy to treat others lower on the hierarchy with disrespect'.[700] Since hierarchy in medicine exists, those at the bottom of the ladder are typically expected to 'earn' their position by being silent and without speaking up or challenging more senior colleagues.[701] Therefore, for any intervention to be effective, it may be necessary to meet stringent requirements and ensure that a regulation process does not fail. A single action might not address the complexity of the problem. This can be adapted to the failure of the MMC as the problem may lie within the social ranks between doctors, patients, the MMC and the courts which have failed to address this issue due to many hierarchal levels that are in place. The practice of granting patient access to their medical records cannot truly be reformed while these social hierarchies continue to exist.

Black is also interested in the various rationalities and communicative logic that exist inside the regulatory space such as legal logic, administrative logic and medical logic. The various lenses through which actors observe, think and act and their diverse and frequently conflicting interests shape the regulatory landscape. As a result, the regulatory space argument introduces many variables that could influence the development of public policy and regulation by governments and social actors. In healthcare provision, stakeholders are expected to hold different judgements, beliefs and expectations but concepts such as complexity, fragmentation

[700] Matthew Grissinger, 'Disrespectful Behavior in Health Care: Its Impact, Why It Arises and Persists, and How to Address It—Part 2' (2017) 42 Medication Errors 74, 74.

[701] Muhammad Siyab Panhwar and Ankut Kalra, 'Breaking Down the Hierarchy of Medicine:The Airline Industry Has Taken the Lead to Improve Communications for Pilots, It Is Now Time for Medicine to Follow with Physicians' (2019) 40 European Heart Journal 1482, 1482.

of knowledge, fragmentation of power and non-recognition of autonomy can lead to a failed or suboptimal regulation.[702]

For example, fragmentation causes information asymmetry between the regulator and the regulated. Fragmentation of power highlights the regulatory problems and the nature of the regulatory space in Malaysian society within this social hierarchy and the broad influence it has on access to medical records for patients. Different actors have different forms of command and control and medical professionals continue to enjoy the privilege of higher authority with unrecognised or fragmented knowledge over the patients' right to access. While the MMC Guidelines exist as standards, a default practice becomes routine and receives a social mandate due to the failure to recognise it as an issue that erodes patients' right.

Black also states that the 'government' or 'higher authorities' cannot fully understand an industry as much as the industry does itself.[703] The healthcare system is its own entity and despite the professional hierarchies that exist, remains in constant and dynamic interaction with the most important stakeholder; the patients. The regulation of access to medical records is a space of complexity that no single actor can fully understand (fragmentation of knowledge). For example, patients might know of their right to access medical records but as the record belongs to the hospital, they do not understand why permission is required to access this right. Meanwhile, policymakers or legislators may have a different perspective and might not be able to fully 'know' what constitutes patients' rights as being absolute and not defined in policies or the law. Black also described that no single actor, including an expert, has all the knowledge to solve complex and dynamic problems.[704] It is therefore unreasonable to exclude patients as part of the knowledge-seeking process and in Malaysia, the information asymmetry seems

[702] Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World', 108.
[703] Ibid 107.
[704] Ibid 107.

more apparent due to the lack of patient participation compared to other healthcare systems such as in the UK.

Gunningham claims that 'the use of multiple rather than single policy instruments and a broader range of regulatory actors, will produce better regulation'.[705] One of his regulatory designing principles which allow policymakers to take advantage of this strategy is empowering third parties to act as 'surrogate regulators'[706] to achieve better outcomes where there are no alternatives to direct government intervention, something to which we will return later.

### 7.3.2 Complexity of the regulatory space: Interaction between stakeholders

I have briefly discussed Black's concept of decentred regulation and several of the factors she describes as the causes of regulatory failure. I have also identified such failures in the domain of access to medical records. Now, I consider the concept of 'complexity'[707] which fits with the discussion of the nature of the Malaysian regulatory space, especially on patient access. Black describes complexity as the interaction between actors and society and the 'constant tension' that is created by the social problems these interactions generate.[708] Malaysia has a dichotomous public and private healthcare system. I have previously mapped the regulatory domain of patient access and the different state actors between private and public providers. These differences in the two-tier system pose challenges and thus the domain of patient access will be challenged by these actors, including how they interact, what rationalities they use, what values they work by, what outcomes they generate from their interactions, and the extent to which they can influence others in this space (see Chapter 2).

---

[705] Gunningham and Sinclair, 'Smart Regulation', 133.
[706] Ibid 144.
[707] Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World', 106.
[708] Ibid 107.

As a result of this two-tier system, the Malaysian government is deeply involved in the regulation of healthcare although the system is rapidly evolving. The MoH and the MMC limit their authority and do not apply themselves to private clinics and hospitals. Neither the MoH nor the MMC has the jurisdiction to impose restrictions on right to access on private medical practitioners, as neither the Medical Act 1971 nor the MMC Guidelines provide for such actions.

The asymmetrical regulation that already exists in Malaysia may have major implications in healthcare. It can cause confusion as to what defines standard practice including services involving patient advocacy. For example, PHFSA and its Regulations exercise regulatory functions to ensure private healthcare services provide good healthcare to patients, including patient access.[709] Regulation 44 of the PHFSA sets out a particular approach to the right of patients to access medical records stating that, 'No patient's medical record shall be taken out from the private healthcare facilities […] except under a court order'.[710] Thus the Act has had a substantial impact on public understanding of their rights when seeking treatment in private institutions but it does not apply to public institutions. Any recommendations to change this discrimination must include a standardised approach to ensure that undifferentiated issues such as patient access are universally applied.

Another complexity that influences the Malaysian regulatory space is the one between patients and doctors. This can be applied to the empirical evidence on the outcomes of patient access (see Chapter 4) and the accompanying discussions relating to the inherent gap between the perceived and real effects of allowing patient access from doctors and patients. The usual practice of obtaining access through court orders in Malaysia also leads to potential litigation

[709] Refer to Private Healthcare Facilities and Services Act 1998; Private Healthcare Facilities and Services Regulation 2006.
[710] Private Healthcare Facilities and Services Regulation 2006.

against the medical professional. These factors are examples of the constant tension or friction that influences how this practice is regulated. For example, it has been shown that litigation can have a destructive emotional impact on doctors in medical negligence disputes[711] and create predictable hazards which have important implications for healthcare providers and law reform. While complexity in regulation is not always avoidable, this may further affect how an issue is regulated.

According to Black, different actors continue in a constant dynamic way 'to develop or act in their own way in the absence of intervention'.[712] Regulation cannot take the behaviour of those being regulated as constant. She claims that this has several ramifications, the first of which is that regulation would result in unanticipated (albeit not necessarily negative) changes in behaviour and outcomes, which is a well-known empirical phenomenon in regulation. In Malaysia for example, patient access is determined by the doctors and healthcare providers who own the medical records and they have a tendency to restrict patient access by allowing patients to access through a court order. Second, depending on the regulatee's attitude to compliance, its structure may need to vary. Again, this reflects the practice of patient access through court order due to the lack of the regulatee's (doctors and hospitals) to comply with the MMC Guidelines. Third, no single actor can unilaterally dominate the regulatory process since all are restrained in accomplishing their own aims not just by their own knowledge limitations, but also by others' autonomy.[713] In Malaysia, the doctor's autonomy prevails despite the MoH's emphasis on patient-centred care as a component of healthcare delivery. The MMC Guidelines on doctors' duties including collaborative partnerships as a goal of doctor-patient relationships, the theory and practice of increased patient involvement remain

711 Angelo Antoci, Alessandro Flori Maccioni and Paolo Russu, 'The Ecology of Defensive Medicine and Malpractice Litigation' (2016) 11 PLOS One e0150523, 10.
712 Black, *Critical Reflections on Regulation*, 4.
713 Ibid 5.

in their infancy. One of the major reasons for this is that there is an impermeable social hierarchy in Malaysian society: politicians, elders, religious scholars, educators and doctors enjoy higher authority. Therefore, these different actors hold different unrecognised autonomies that constrict the practice of patient access in Malaysia as per Black's theory.

In the matter of autonomy, Black also states that unrecognised autonomy is another factor of regulatory failure. The Malaysian regulatory space where actors, events and processes interact to create a busy environment of change, risks crowding out more improved responses and disincentivising the actors to act responsibly due to the imbalance of power and lack of patient empowerment. Cultural influence shapes the regulation and society that exists in Malaysia which, as a multicultural society, has distinctive multicultural elements that influence its social systems, including in healthcare.[714] Researchers have identified five cultural components related to Malaysian patients and healthcare providers.[715] One of these is medical paternalism in the doctor-patient relationship. The others are different religious beliefs, strong family involvement, language differences and traditional complementary medicine that influence clinical decision-making.[716] This diversity creates different cultures as an unrecognised autonomy to address optimal health outcomes for different players from different backgrounds.

This regulatory domain is also typified by struggles and conflicts. Hancher and Moran propose that the central importance of the form of regulation is deeply influenced by the, 'particular conception of the scope and purpose of law which prevails in any particular community at any particular time'.[717] In Malaysia, the main purpose and character of patient access is to seek malpractice or pursue litigation. This creates the question of who benefits from the regulation

[714] Abdul Rahman Embong, 'Malaysia as a Multicultural Society' (2002) 12 Macalester International 37.

[715] Yew Kong Lee and Chirk Jenn Ng, 'The State of Shared Decision Making in Malaysia' (2017) 123-124 Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 66, 67.

[716] Ibid 66-67.

[717] Hancher and Moran, 'Organising Regulatory Space'.

and culturally allows the assumption that the roles of hospitals and doctors and of patients in the regulatory space can be distinguished. The actors that occupy this regulatory space are constantly involved in the 'ferocious struggle for advantage',[718] either for the distribution of power or resource leading to aspects of relationships between those who enjoy inclusion and those who are excluded.[719] This can be applied in a clinical setting in which different expectations from healthcare providers and patients are common.[720] In matters of patient access in Malaysia, patient-centred objectives such as patient empowerment and self-determination seem to be excluded.

As the main authoritative bodies and policymakers, good cooperation and strong relations between the MoH and MMC are needed. As seen in medical litigation (see Chapter 2), requests to access medical records without court orders are refused by hospitals.[721] This has become habitual and normalised, endorsed by providers and not challenged by patients, and is configured around the formal legal processes which explains why the scope for patients to access their records is narrow. As getting a court order is not available to everyone given the expense and protracted timeframe, using theories of regulation will identify different regulatory levers to manage access. These reforms address the problems that flow from configuring patient access to medical records around legal mechanisms. Proposing new legislation to provide this right would not change the cultural aspects and so any reform, including legal sanction, must play as an adjustment mechanism between the social coordination that traditionally dictates the doctor-patient relationship and being forward-looking to ensure

[718] Ibid 153.
[719] Ibid.
[720] Carlos El-Haddad, Iman Hegazi and Wendy Hu, 'Understanding Patient Expectations of Health Care: A Qualitative Study' (2020) 7 Journal of Patient Experience 1724.
[721] Refer to *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*; *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*.

sustainability and comparable to the standards delivered by other healthcare systems such as the NHS.

In this chapter, I have discussed some regulatory challenges made in Malaysia after mapping the regulatory space that influences patient access in Chapter 2. While a comparative analysis with the UK suggests that law can help, the social-historical framework in which the doctor-patient relationship happens in Malaysia remains paternalistic and doctor-centric, as seen by the guidelines and practice relating to this issue. Decentring regulation can allow multiple ways of regulation and different actors can employ power and improve autonomy so that their point of view becomes part of the 'know-how'. Legislation as a reform tool might work, but it will have to cater for and be comprehensive enough to address all these conflicts of interest and address the agendas and motivations as well as act as a force for decentred regulation.

### 7.3.3 Legislation as a reform tool to change behaviour

Legislation may be the long-term answer to providing more automatic patient access. In Chapter 2 we saw that there is no formal law recognising patient access as a defined right and that '[t]he prevalent common practice among medical professionals and hospitals is to refuse to give copies of patient's medical records unless ordered by the court to do so'.[722]

The law imposes obligations under the social assumption of justice and therefore can be viewed as a legitimate and reliable source of behavioural change in healthcare providers to allow patient access. However, the law cannot guarantee the reformation of values and beliefs with specific practices. In Chapter 5, I considered the ethical justifications for widening patient access and concluded that the practice should be encouraged within an ethical framework to deliver a behaviour change. Legal regulation can force compliance in the short term and when combined with a change in attitudes using non-regulatory measures, will render the law

[722] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

legitimate in the long term. This will prompt the community members (especially healthcare providers) to improve cooperation with patients as part of their moral imperatives based on strong ethics for a more viable practice.

Blis and Nadler state that, '[u]ndoubtedly, laws are sometimes effective because they are backed by the threat of punitive enforcement'.[723] Individuals are encouraged to consider the risks and benefits before deciding whether or not to engage in prohibited behaviour and refrain from so doing. According to Wellman:

> Legislation, at least in a democratic society, reflects and is supposed to reflect, a compromise between the diverse preferences and interests of the members of that society [...] Hence, a legislative acceptable compromise can be attained only if some considerable degree of moral agreement can be achieved during the course of the political debate.[724]

Another aspect is that introducing new legislation may work on the behavioural aspect. Should legislation be introduced to grant wider patient access, the legislation will, over time, ensure it becomes normal practice, changing behaviour in all stakeholders to allow and facilitate access without the need to depend on legal intervention. Inevitably this will result in reducing the tendency to use the law to resolve conflicts.

While legislation is useful, it is not the absolute solution to widening access because the common law in Malaysia already recognises the patient's right to access their records. In proposing recommendations to improve patient access, but without increasing legal intervention, a definitive legal mandate can codify the common law principles so that the action is taken to compartmentalise principles such as the right to access and to enshrine them in legislation. Inevitably, despite the recognition of patient right to access medical records, the

---

[723] Kenworthey Bilz and Janice Nadler, 'Law, Moral, Attitudes and Behavioral Change' in Eyal Zamir and Doron Teichman (eds), *The Oxford Handbook of Behavioural Economics and the Law* (Oxford University Press 2014), 245.

[724] Carl Wellman, *Moral Consensus and the Law* (Dorrecht: Springer 2011).

challenge is to increase compliance and shift mindsets as well as attitudes towards acceptance of wider patient access.

## 7.4 Conclusion

Using Black's work on decentralised regulation, this chapter has discussed the concepts of regulatory failure and attempted to map out the regulatory space in Malaysia that portrayed the elements of the fragmentation of power and knowledge and unrecognised autonomy as causes of regulatory failure in a state-centric government. The social-historical environment in which the doctor-patient relationship sits in Malaysia is still paternalistic as evident in the guidelines and practice on access. Therefore, I argue that a change where patients are to be more empowered, and doctors are a conduit for information transmission can only happen if there is involvement and cooperation from all the actors involved.

When the law imposes obligations and punishment in concordance with general intuitions about moral virtue, the public is likely to view it as legitimate and as a reliable source of morality. It is hard to identify the determinants motivating the current practice in Malaysia as there are no relevant studies, but it can be concluded that there is a lack of dialogue and awareness of the moral reason why patients should be allowed automatic access. In particular, we have seen that the insecurity and concerns over being completely honest cause hesitancy in healthcare providers and the lack of education on patient-centred care in a nurtured but unequal doctor-patient relationship reduces the perception of the legitimacy of the law and regulation in this matter. Therefore, legislation alone might cause a negative outcome; a lack of legitimacy in which the legal profession is assumed to have more power than the formal authority of doctors and health institutions and the public is increasingly expected to 'behave' as legal

subjects. This is already evident in current practice in Malaysia with court orders as the default to access medical records.

It is not the legislation *per se*, but the legitimacy of the legislation that is more important in driving change, coupled with all the other considerations including education, awareness and cultural reformation. Legislation therefore should operate as a 'pragmatic solution'.[725] It is an important tool to govern and regulate the patriarchal nature of doctors that common law has failed to emphasise[726] and will provide the kind of certainty that is necessary for a society like Malaysia where other concerns such as patient autonomy remain unfamiliar. In a situation where legal avenues have become the solution for such conflict, the sustainable solution is to discourage patient access to medical records contingent on court orders, and to make it a norm.

[725] G Pennings, 'Reproductive Tourism as Moral Pluralism in Motion' (2002) 28 Journal of Medical Ethics 337.
[726] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*; *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*.

# Chapter 8. Recommendations to widen patient access

## 8.1 Introduction

As we have discussed, the MMC lacks the regulatory power to enforce its Guidelines and the current legislation is too ambiguous, resulting in the current practice of seeking a court order. In healthcare provision, stakeholders including patients should influence the regulatory environment but unfortunately, the concept of patient empowerment is still in its infancy and is further worsened by doctors who are resistant to change or recognise patients' rights. Doctors in Malaysia continue to enjoy the privilege of authority presumably due to fragmented knowledge over patients' right to access and unrecognised autonomy. Complexity also arises in the two-tier system with different policies on patient access in the public and private sectors.

The regulatory impediments to widening patient access necessitate a set of recommendations to improve automatic granting of patient's request for access (see Chapter 2). Such recommendations would encompass the regulatory mix that must be considered for the change to be successful. These recommendations emphasise a reform to introduce measures to produce a stronger legal and ethical standing for patient access in both state and non-state facilities consisting of both legal and non-legal approaches. As a whole, they provide a decentralised and society-oriented means of regulation as a long-term and forward-looking solution as well as bring about the behavioural changes with which automatic granting of patient access will become the norm.

## 8.2 Recommendations at the state level

### 8.2.1 Recommendation 1: Defining and protecting patient's legal right to access medical records

Although Malaysia has pursued the statutory path of developing its own personal data protection legislation, unlike the UK's DPA and AHRA which extend the right of access to cover the healthcare sector and specifically state that personal data can be in the form of 'health records', Malaysia lacks such a provision. As we have seen, the PDPA is insufficient because it does not define 'personal data' as 'health records' or 'medical records', which leads to misinterpretation and arguments. Despite the enactment of the PDPA which allows data protection to be implemented in a variety of industries including healthcare, banking, finance, telecommunications and the media, it does not appear to cover all aspects of data protection in the healthcare setting. Given that the PDPA is unhelpful due to the lack of specification on what constitutes personal data and whether it includes the data in medical records,[727] Malaysia should have a separate bill that covers access to health records. This could come in several forms.

#### 8.2.1.1 Improving legal protection through bills

Access to patients' medical records is continually developing and the right to access have been increasingly recognised in many countries including Malaysia. However, as we have seen, common law on its own is inadequate to bridge the gap in providing definitive legal protection for patient access. *Nurul Husna*[728] failed to fill the void in recognising the right of patient access and this was followed by *Nur Syafrina*,[729] both discussed in detail in Chapter 2.

[727] Refer to Personal Data Protection Act 2010.
[728] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.
[729] *Nur Syarafina Sa'ari v Kerajaan Malaysia & Ors*.

Legislation is a strong lever to regulate this practice and offer legal protection of this right, due to the certainty, gives clarity and stabilises expectations.

I am proposing a new bill for Malaysia which should be based on the model in the UK's AHRA 1990. Under this provision, patients would not need to resort to making an application to the court to obtain their medical records. The need for this bill is compelling and a law based on the AHRA will be contributory as Malaysia lacks specific legislation protecting patients' right to access their records. This necessitates a statutory form of action to build on the common law.

While patient access to medical records is the main focus of this thesis, previous debates around privacy have been raised. Although this thesis does not seek to examine privacy issues in detail, there a are number of considerations arising from it. Laws and regulations are crucial to keeping the patient's health records confidential and private. Widening access to records will affect or create legal problems which will need careful consideration by both policymakers and academics. There are potential issues in the area of privacy that policymakers may have to confront as a result of widening access such as new laws and guidelines as the lack of privacy protection in Malaysia is still an issue. There is also a need to balance how much information is to be revealed to the patient and the intellectual property rights of the doctors. As technology continues to advance, it will improve not only the comprehensiveness of access but also the ease of access. The new law will need to keep up with technological advances so that the law is not ambiguous and does not leave loopholes in addressing the privacy, security and rights of patients, not only in the current but also in the future forms of technology like EMRs.[730] Technology assists patient access but involves aspects of confidentiality and privacy of the

[730] Jawahihta Sarabdeen and Mohamed Mazahir Mohamed Ishak, 'E-Health Data Privacy: How Far It Is Protected?' (2008) 1 Communications of the IBIMA 110, 110.

information. Therefore, the proposed bill must afford legal protection on technology use, both now and in the future.

Although the Malaysian Federal Constitution lacks a specific provision on the topic of the right to privacy, it has been recognised as a fundamental human right at the international level and is protected by Article 12 of the Universal Declaration of Human Rights 1948 (UDHR).[731] The Federal Constitution of Malaysia ensures that the fundamental liberties of Malaysians are guaranteed in Articles 5-13 which includes the basic human rights principles stated in the UDHR.[732] However, the Constitution is silent on the right to privacy. In the landmark case of *Ultra Dimension Sdn Bhd v Kook Wei Kuan*[733] in 2004, the Court held that the right to privacy is not recognised under Malaysian law.[734] However, other courts in Malaysia are more inclined to recognise the right to privacy in healthcare.[735] Article 5 of the Constitution states the fundamental right to liberty of an individual but nothing on the right to privacy. The position changed in the Federal Court in *Sivarasa Rasiah v Badan Peguam Malaysia* when the Court held that this included privacy.[736] Therefore despite Malaysia striving to provide some sort of

---

731 Universal Declaration of Human Rights 1948.

732 Federal Consitution of Malaysia 2010.

733 *Ultra Dimension Sdn Bhd v Kook Wei Kuan* [2004] 5 CLJ 285

734 Ministry of Health Malaysia, *Private Medical Practice Control* (Government of Malaysia). The Court held that: 'it is clear that English Common Law does not recognise privacy rights and it therefore follows that invasion of privacy rights does not give rise to cause of action. As English Common Law is applicable in Malaysia pursuant to Section 3 of the Civil Law Act 1956, privacy rights which is not recognised under English Law is accordingly not recognised under Malaysian law. Thus, the respondent does not have the right to institute an action against the appellant for invasion of privacy rights'.

735 *Lee Ewe Poh v Dr Lim Teik Man* [2011] 4 CLJ 397 . The court for the first time had departed the views taken by other courts and found that the right of privacy is considered a recognisable cause of action under the Malaysian law. The case involved the patient (plaintiff) who suffered from haemorrhoids and consulted the doctor (defendant) for removal of the haemorrhoids. The plaintiff found out from a nurse that the defendant had taken photographs of her private parts while she was under the general anaesthesia. She sued the defendant on the ground of invasion of privacy and dignity. The court held:" The privacy right of a female in relation to her modesty, decency and dignity in the context of the high moral value existing in our society is her fundamental right in sustaining that high morality that is demanded of her and it ought to be entrenched. Hence, it is just right that our law should be sensitive to such rights. In the circumstances, the plaintiff in the instant case ought to be allowed to maintain such claim".

736 *Sivarasa Rasiah v Badan Peguam Malaysia* [2010] 2 MLJ 333 .The Court held that Article 5(1) of the Federal Constitution which guarantees that 'no person shall be deprived of his life or personal liberty, save in accordance with law', encompasses the right to privacy. The Court of Appeal also interpreted the right to privacy in *Tan Tek Seng V Suruhanjaya Perkhidmatan Pendidikan* [1996] 1 MLJ 261 . The case concerned the allegedly wrong dismissal of Tan Tek Seng, a senior assistant of a primary school. In ruling in his favour, the

protection for health data privacy, the lack of privacy law may be a hindrance considering the challenges posed by technological innovations[737]. There is a need to institute laws and regulations that are in step with these developments. The recent advances in Malaysian courts were in favour of privacy protection on the invasion of privacy but whether it would provide appropriate protection and whether specific privacy law is thus justified, given it was introduced in the common law and despite being absent in the Malaysian Constitution. Hence, protection is required not only to protect the current setup but also as technology continues to advance providing new means and measures to accessing the records which may lead to the information being vulnerable to access by third parties. Therefore, the privacy law must be comprehensive so that it is unambiguous in addressing privacy, confidentiality and security of patient access.

#### 8.2.1.2 Need to improve the Malaysian Personal Data Protection Act 2010

One shortcoming of the PDPA is that personal data can only be used for commercial organisations and so does not apply to medical records in a public healthcare system as it is a non-profit-making exercise thereby making the enterprise non-commercial. This is a major limitation to obtaining the data in medical records and leaves a major gap in the law.

The Act also fails to properly define what constitutes a 'commercial transaction' and while a private hospital may be profitable in nature, the public hospitals which rely on subsidies and provide healthcare as a service may be irrelevant. Hence the Act needs to be amended to apply to personal data for all purposes.

---

Court of Appeal held that Articles 5 and 8 of the Constitution, which protect personal liberty and equality under the law. 'The expression 'life' appearing in Article 5(1) does not refer to mere existence. It incorporates all those facets that are an integral part of life itself and those matters which go to form the quality of life'.

[737] Effy Vayena and others, 'Policy Implications of Big Data in the Health Sector' (2017) 96 Bulletin of the World Health Organisation 66, 68.

The non-applicability of the PDPA to Federal and State Governments also raises the question of the different standards of data in public and private institutions. As a result, protection is limited and unavailable to the greatest data consumer in healthcare: the Malaysian government, which owns the public health facilities and the Act is ineffective as a resource for patients seeking access to their medical information. To avoid a double standard in the management of data, the Act should be inclusive of both state and federal governments, offering full protection for personal data universally at different levels of society.

### 8.2.2 Recommendation 2: Integrated health regulation

Although the public sector provides 82 per cent of inpatient care, while the private sector provides 18 per cent,[738] the PHFSA is only imposed on doctors in the private sector with no similar imposition applied in the public sector. As a result, patients in the private sector are protected by statute, whereas patients in the public sector are not. This rule is disputed and unenforceable because it has no binding effect on Malaysian public hospitals. Integration of health regulation to include either an Act or Guidelines that apply to all healthcare providers is required. There are significant differences in patient access which include requiring the hospital Director's permission or that patients seek a court order for access, enshrined in the MMC and MMA guidelines. If legislation and guidelines are introduced to address patients' right to access, this must apply to both sectors. It is unreasonable to continue the existing regulatory framework in which the MMC regulates and registers medical professionals including those practising in private sectors but does not extend its authority and guidelines to private providers.

Closer engagement, collaboration and integration between different regulatory bodies are required to ensure standardised regulation that applies to both sectors. In addition, an integrated

[738] Safurah Jaafar and others, *Malaysia Health System Review* (Health Systems in Transition, WHO Regional Office for the Western Pacific (2012), 15.

system of medical information and expertise to advise how information is managed and accessed could improve the cohesion and compliance of practices such as granting patient access. Although Malaysia can continue to provide healthcare with its current dual-tiered system, it should strive for egalitarian healthcare regulation so that patient access is regulated in a standard manner.

### 8.2.3 Recommendation 3: Dual ownership

To resolve the regulatory impediments arising from the ambiguity of ownership of medical records,[739] medical records unlike other documents should not be a 'single owner' document. Rather they should be considered co-owned by both the patient (who is the subject of the records) and the doctor or healthcare provider (who generates and has custody of the records). The guidelines and case law in Malaysia have demonstrated that medical records belong to both, although the MMC states that the physical property of medical records lies with the doctors but also ethically and morally with the patients, illustrating the conflicting position to safeguard both interests. However, despite this attempt to address the position on ownership by addressing both parties, the MMC has tipped the balance in favour of the doctors. Because of its purpose of providing healthcare personnel with access to medical records as a part of their duty while also protecting sensitive information by limiting access, patients' right of access to medical records have been undermined. The concept of 'legal ownership' needs to achieve clarity of who owns the records without restricting access.

To achieve this, I propose a model adapted from Ombrellaro et al.,[740] a patent design application published in the US, to solve the issue of dual ownership. While the patient is the owner of their personal health information, the healthcare provider generates the information

[739] Mark P Ombrellaro, 'Access Control in an Electronic Medical Record System' (2007) Patent Application Publication .
[740] Ibid 3-4.

and controls the documents. The patient has unrestricted access to read and review their medical information under the dual ownership system and the right to acquire a copy of their medical information from the healthcare provider. This dual ownership approach combined with the transition to digital medical record systems raises important questions about the control and security of healthcare medical records and giving and regulating access to medical information. Although the patient owns the information, the information created by the doctors should not be modifiable by the patient or others who have access. The patient may also wish to grant limited access to non-medical third parties such as legal guardians and legal professionals under certain circumstances. It is forward-thinking and ethically justified if we include consideration of immediate and direct access by patients.

If Malaysia was to adopt the Ombrellaro approach, the model may be adapted by proposing two modes of access. The model reflects ethical considerations of benefits against harms (see Chapter 5):

1. **Account Owner Access** which gives access to the medical record account given to each individual patient as they are the owner of the personal information. It is anticipated that there is only one true owner for each account. This access allows full unrestricted 'read-only' access to all personal information within that account and cannot be disabled[741].

2. **Author Access**, where the creator of medical records who is deemed the owner of the documents is granted access. The doctor who has access to the account can read the whole record and produce new medical documents to be added to the account. They have unrestricted access to change or add data to any area of the medical record. When a change to a medical record is made and saved, it

[741] Ibid 3-4.

creates a permanent entry with the date and author recorded. Any modified or deleted data is archived in a retrievable manner[742].

I propose that this is the future landscape of EHRs with immediate, real-time access to all stakeholders including patients. While the limitations of this model are beyond the scope of the thesis, we can envision that the benefits and problems of EHRs (see Chapter 1) will encourage this practice. However, the accessibility of the EHR across hospitals raises the possibility of dual ownership being successful. The doctor, as the recipient of the information, has the duty to keep the information confidential and sharing the patient's information with third parties requires the patient's consent. This thesis earlier raised the question of whether doctors should limit patient access when the privacy of the doctors or their clinical judgement as part of intellectual property may be compromised. The MMC Guidelines claim the record is the intellectual property of the doctor who has generated it but ethically and morally belongs to both doctors and patients.[743] It is, however, not straightforward as the contents of the records might cause harm to the patient. Therefore, with the proposed improved patient access, doctors and healthcare providers must still navigate data accessibility based on clinical judgement without restricting patient autonomy. One solution is that access is granted with certain restrictions in which dual or single ownership of personal information may depend on property information and whether it is connected to one's privacy as the recognised owner of that property. As technology advances and the exercise of accessibility and restriction becomes more complex, this may create the concept of legal ownership which may achieve more clarity to regulate further access to different parties.

---

[742] Ibid 3-4.

[743] Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports*, cl 1.12.

### 8.2.4 Recommendation 4: A fiduciary duty between doctors and patients

A fiduciary is a person in a position of trust and confidence to put the interests of the principal above their own personal interests in a fiduciary relationship.[744] The proposal of a fiduciary duty between doctors and patients encourages a relationship based on partnership, obligations and openness which are the ethical arguments used in this thesis to widen patient access. O'Neill describes the fiduciary relationship as a 'paradigm of a relationship of trust'.[745] She also argues that doctor-patient relationships are 'viewed as relationships of trust only because a paternalistic view of medicine was assumed, in which dependence of patients on professionals were generally accepted'[746] and this might very well work in Malaysia given medical paternalism continues to prevail. Rogers states that in a General Practice relationship, 'without trust, we cannot seek or provide healthcare'.[747] Allowing patients access to medical records has been described as a foundation for developing a 'partnership of trust' [748] with patients.

A fiduciary relationship imposes certain duties on the fiduciary or trustee because of the vulnerability of the beneficiary and the power imbalance between the two. Brazier and Lobjoit state that the relationship of trust 'encapsulates the very heart of the doctor-patient relationship'[749] and is 'best represented by developing the concept of the fiduciary relationship between patient and professional'.[750] Although a fiduciary relationship requires trust as a

---

744 Deborah A Demott, 'Relationship of Trust and Confidence in Workplace' (2015) 100 Cornell Law Review 1255, 1259.
745 Onora O'Neil, *Autonomy and Trust in Bioethics* (Gifford Lecturers, Cambridge University Press 2002), 17.
746 Ibid 18.
747 Wendy A Rogers and Annette J Braunack-Mayer, *Practical Ethics for General Practice* (Second edn, Oxford University Press 2009), 29.
748 Amir Hannan and Fred Webber, 'Towards a Partnership of Trust' (2007) 127 Studies in Health Technology and Informatics .
749 Margaret Brazier and Mark Lobjoit, 'Fiduciary Relationship: An Ethical Approach and a Legal Concept? ' in Rebecca Bennett and Charles A. Erin (eds), *Hiv and Aids : Testing, Screening, and Confidentiality (Issues in Biomedical Ethics)* (Oxford University Press 1999), 187.
750 Ibid 187.

necessary condition of the relationship, a power imbalance exists as the principal feature of this relationship.[751] The fact that this relationship is founded on trust and confidence and whether the doctor is a trustee for the patient's medical welfare can be questioned when doctors' acts are paternalistic to protect the patients from harm mentally or physically if the information in the medical records is disclosed.

Beauchamp and Childress state that '[t]he patient-physician relationship is a fiduciary relationship that is founded on trust or confidence; and the physician is therefore necessarily a trustee for the patient's medical welfare'.[752] However, an important consequence of attaching fiduciary duties to the doctor-patient relationship is that patient autonomy could be undermined by the objective of a fiduciary duty which is to pursue the patient's best interest with good faith and loyalty based on the doctor's expert advise. [753] Therefore, the fiduciary model is flawed as within an inherently paternalistic system it cannot foster the independent rights of patients and their autonomy. However, it is precisely this flaw that might work in Malaysia due to the inherent and well-established patriarchal nature of the doctor-patient relationship. Fiduciary relationships are not equal and therefore might be more natural and acceptable for medical professionals in Malaysia where the hierarchical order of the doctor-patient relationship prevails.

Canada introduced fiduciary duty and it is compulsory for the doctor to act in a fiduciary manner (See Section 3.5.2) .[754] Malaysia has also subscribes to fiduciarity in the common law, which was applied in *Nurul Husna*.[755] Fiduciarity may cause a conflict of interest and doctors may find themselves in the position of choosing between self-interest or the patient's interest.

---

[751] Rosemarie DLC Bernabe and others, 'The Fiduciary Obligation of the Physician-Researcher in Phase Iv Trials' (2014) 15 BMC Medical Ethics 1, 4.

[752] Beauchamp and Childress, *Principles of Biomedical Ethics*, 312.

[753] Ross and Stratton-Lake, *The Right and the Good*.

[754] Refer to *Mcinerney v Macdonald*.

[755] Refer to *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

This can easily occur with a patient's request to access medical records, especially in possible malpractice or litigation. However, restricting access is already a breach in the doctor-patient fiduciary relationship due to the nature of the relationship that emphasises the patient's best interest. Thus, while the UK has not subscribed to the fiduciary duty, Malaysia's inclination to slowly shift ultimate responsibility for patients to make decisions with doctors still enjoying the high hierarchy of social order in the healthcare system could make this a supplemental model for decision making unique to the Malaysian experience. While opponents of fiduciaries see this as a compromise to patient autonomy (and maybe the reason why this has not been adopted in the UK), fiduciary duty is still compatible with patient autonomy when requested on the patient's behalf.[756] For example, a doctor's duty to provide access to medical records is ultimately grounded in the need to serve the patient's interests. The doctor's position is one of trust and confidence. While the doctor is the owner of the record, the information in it is to be used by the doctor for the benefit of the patient. The confiding of information to the patient for medical purposes gives rise to an expectation that the patient's interest in and control of the information will continue. The trust-like 'beneficial interest' of the patient indicates that they should have the right of access to the information and the doctor should have a corresponding obligation to provide it.

Patients should obtain adequate material knowledge regarding all situations in the medical records, according to fiduciary standards, ethical norms and legal precedents that respect patient autonomy. This will allow patients to use the information in making informed decisions. As the doctor has little control over whether the patient's interest especially in regard to emotional harm will be affected by information which includes potentially unwelcome news,

[756] Ben Davies and Joshua Parker, 'Doctors as Appointed Fiduciaries: A Supplemental Model for Medical Decision-Making' (2022) 31 Cambridge Quarterly of Helthcare Ethics 22.

it is up to the doctors to decide what information should be disclosed, although their choices are constrained by ethical and regulatory requirements.

This will be tricky to establish. Fiduciarity should be from the doctor's conscience rather than forced upon them and can only be trained and tempered through experience. Thus, the proposition is to educate doctors to instil fiduciarity in the thought process and in their everyday practice.

### 8.2.5 Recommendation 5: Optimising EHR

EHRs are being increasingly implemented in Malaysia. As previous research[757] shows that the trend of HIS adoption is low for Malaysian public hospitals, there is however a growing adoption of information technology in the Malaysian healthcare industry. Of 141 public hospitals in Malaysia, 30 are tertiary-level hospitals but only 16% are fully equipped with THIS with a delay in adopting the HIS technology elsewhere.[758]

In countries such as the US, a significant benefit of EHR has been to provide a platform for easier access for patients[759] whereby their personal health record can, 'be drawn from multiple sources while being managed, shared and controlled by the individual'.[760] EHR are becoming more common, especially with multidisciplinary management as part of standard practice for many chronic illnesses. It is therefore important to have real-time and easily accessible health information using digital technology.[761] Similarly, Malaysia is moving towards the greater use

[757] Ismail, 'Adoption of Hospital Information System (HIS) in Malaysian Public Hospitals', 336.
[758] Ministry of Health (2014).
[759] Carlisle George and Diane Whitehoyse, *Ehealth: Legal, Ethical and Governance Challenges* (Springer 2013).
[760] US Department of Health and Human Services, *The National Alliance for Health Information Technology Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information Technology Terms*, (2008), 6.
[761] Robert J. Blendon and others, 'Common Concerns Amid Diverse Systems: Health Care Experiences in Five Countries' (2003) 22 Health Affairs 106, 120.

of digital technologies. Under the 12th Malaysia Plan, the framework has been set for an interlinked EHR between all public hospitals.

However, the essence of accessibility of medical records and the information it contains, especially if granted in real-time, lies in the technology that allows access. While health professionals can use a digital platform to create records from different sites, the technology can also help to improve the accessibility and security of patient data. EHRs can be used to encourage access and privacy rules that are already established.[762] Unlike paper medical records where copies and physical location must be considered to facilitate access, EHRs can reduce the risk around issues of privacy if security is prioritised in the system's design with proper regulation of access. For instance, an access control mechanism may be used to set a limit on how much information various users can see. One of the security measures is a record system that reduces the danger of unauthorised access. Here, it is evident that EHRs can facilitate policymakers and healthcare providers in instituting a more comprehensive approach for access to records and provide the technology to improve access and address the inherent problems around access such as privacy and security.

Unlike its Malaysian counterpart, the UK's DPA establishes a regulation for controlling the privacy of all types of personal data.[763] The introduction of EHRs may open opportunities for applying separate right to access different types of information, thereby restricting the information to appropriate users only with the ability to create accessibility-based access controls tailored to an individual's role. If the doctors believe that disclosing the patient's medical history could be harmful, the patient will not have full access. This can be accomplished by using technology to protect elements such as psychiatric disorders or

[762] Yasser K Alotaibi and Frank Federico, 'The Impact of Health Information Technology on Patient Safety' (2018) 38 Saudi Medical Journal 1173.
[763] Personal Data Protection Act 2010.

suspected diagnoses that are yet to be confirmed, allowing dual ownership to be realised. Computers can be set to allow multiple levels of access to information, which is one privacy measure. Doctors, for example, may have access that allows them to examine all the records, while other healthcare providers involved in only one aspect of care can be restricted to the information they need.[764] This requires all healthcare professionals, individually and collectively, to engage in an ongoing effort to identify the best balance between access to electronic health information and the right to privacy of individuals. Standard operating procedures and specific ethical considerations are required to translate the policy's objective and goals into practice that may differ throughout departments and facilities.

Data protection concerns are still present, and they are being addressed as they emerge. With the ability of healthcare facilities such as hospitals and clinics to store patients' data and medical records on computer databases, sharing information in a multidisciplinary setting and secure storage are facilitated. As a result, doctors can deliver better and enhanced services because they can view patients' past histories virtually and instantly. This allows the same platform to facilitate patient access as well.

As Malaysia operates a dual-tier healthcare system, system integration of EHR is a challenging undertaking complicated by uncoordinated planning and legacy and proprietary systems with limited or no networking capabilities.[765] Existing systems must be upgraded, and future information systems must follow standard solutions and integrity models for interoperability, scalability and reusability. Malaysia's model for telemedicine,[766] consisting of four integrated application components, provides a comprehensive framework and a road map for the building

[764] Mohan and Raja Yaacob, 'The Malaysian Telehealth Flagship Application: A National Approach to Health Data Protection and Utilisation and Consumer Rights', 226.
[765] AC Norris, *Essentials of Telemedicine and Telecare* (John WIley & Sons, LTD 2001).
[766] Ministry of Health Malaysia, *Concept Request for Proposal for Lifetime Health Plan: Telemedicine Flagship Application* (Government of Malaysia 1997).

and provision of a future healthcare information system. The MoH must coordinate and regulate existing and future information systems to embrace this framework to ensure that medical data is synchronised across systems and that EHRs are seamlessly and continuously accessible.[767]

The previous proposal to improve privacy laws in Malaysia ties in with the increasing use of the EHR. Policy regarding the confidentiality and privacy of the patient's medical record must be balanced with the appropriateness and the potential benefits of EHR implementation. Laws and regulations are crucial to keeping the patient's health records confidential and private, especially if novel technology is deployed to institute wider access to medical records.

## 8.3 Recommendations at the non-state level

### 8.3.1 Recommendation 6: Improving patient advocacy

As advocacy is important in improving the recognition of patient access to records, an advocacy system should be established. Improving patient empowerment with increasing patient advocacy and participation should be part of the recommendations. Recently, one of the key initiatives in European nations has been to strengthen their efforts in defending patient rights and led to the creation of patient advocacy and patient organisations.[768]

An advocate is 'a person who supports or speaks in favour of somebody or of a public plan or action'[769] and advocacy is defined as 'public support that somebody gives to an idea, a course of action or a belief'.[770] Advocacy encourages the patient to have adequate information

[767] Ministry of Health Malaysia, *National Telehealth Policies: Telemedicine Flagship Application* (Government of Malaysia 2000).
[768] Lars Fallberg and Stephen Mackenney, 'Patient Ombudsmen in Seven European Countries: An Effective Way to Implement Patients' Rights?' (2003) 10 European Journal of Health Law 343, 343-357.
[769] 'Advocate'(Oxford University Press 2018).
[770] 'Advocacy'(Oxford University Press 2022).

required to make an informed decision and promotes the patient's optimal care while also assisting the healthcare team to understand the patient's perspective.[771]

Jan Kremer, a professor of reproductive medicine, once said '[d]on't underestimate the power of patients if you give them the tools. They can do much more than we expect'.[772] Unfortunately, Malaysia's health advocacy is still lacking due to a scarcity of public advocates in civil society. The concept of patient advocacy is still in its infancy and the lack of recognition of public participation as part of the regulation process can be a key component to influence change, individually or collectively.[773]

In a keynote session at the University of Malaya, the deputy Director of the disease control division under the MoH in Malaysia said that failing to develop a systemic approach to develop non-governmental organisations (NGO) in the healthcare system precludes non-state participation that can build the capacity and partnership to improve health advocacy.[774] Another university academic, Professor Rosmawati Mohamed, also highlighted the need for the three C's (connect, communicate and collaborate), which she claimed should be performed using campaigns and persuasive knowledge. Technology and social media can be tools to create and develop health advocacy and establish direct and local patient advocacy and liaison offices.[775]

---

[771] Comfort Nsiah, Mate Siakwa and Jerry PK Ninnoni, 'Registered Nurses' Description of Patient Advocacy in the Clinical Setting' (2019) 6 Nursing Open 1124.

[772] Peter Davies, 'Should Patient Be Able to Control Their Own Records?' (2012) 345 British Medical Journal 24, 25.

[773] Ashswita Ravindran, 'Malaysia's Health Advocacy Still at Infancy Stage: Experts' (2020), accessed 21 January 2022.

[774] Universiti Malaya, 'Building Capacity and Partnerships for Health Advocacy' (*Universiti Malaya,* 2020) <https://um.edu.my/news/building-capacity-and-partnerships-for-health-advocacy>, accessed 23 January 2021.

[775] Ibid. Prof Rosmawati Mohamed is a Consultant Hepatologist at University Malaya Medical Centre and was appointed as founding Co-Chairperson of the WHO Strategic and Technical Advisory Committee for Viral Hepatitis.

The idea of advocacy is not foreign to Malaysia and there is one success story which improved patient advocacy using these themes including social media, technology and establishing a partnership with stakeholders. The Malaysia Hospice supports and promotes the idea of palliative care that includes elements such as human rights, ethics and access to treatment. It raises public awareness about the benefits of palliative care and enhances public knowledge and perceptions about how to deal with life-limiting illnesses and influences policy.[776] As stakeholders, the organisation is involved in planning and implementing national programmes and has commissioned and published 'Palliative Care Needs Assessment: Malaysia'.[777]

As an advocate of patients' information in the US, Julia Hallisy asserts that it is not simply a professional crusade to put medical information into the hands of people but also a personal one,[778] and that patients must become their own advocates. As medical paternalism continues to prevail in the Malaysian healthcare system, patient advocacy and direct participation can instil the value that clinical decision-making and the practice and outcomes of a doctor-patient relationship also involve patient responsibilities. This direct participation can be applied in different levels of the system including local hospitals and the Medical Council. For example, formal complaints about doctors by patients are resolved using a committee that comprises both public and medical members.

The Nursing Board of Malaysia also highlights the roles of advocacy in its Code of Professional Conduct for nurses.[779] Section 1.4 states that when patients are incapable of conveying their demands or safeguarding themselves, nurses must act to promote and protect their interests.[780]

---

[776] Hospis Malaysia, 'Advocacy' (2018), accessed 15 November 2021.

[777] Winy Yeap Sekhar and others, *Palliative Care Needs Assessment Malaysia*, (2016).

[778] Christina Farr, 'Patient Advocates Fight for Access to Medical Data: 'It's a Matter of Life and Death"(<https://www.kqed.org/futureofyou/2519/patient-advocates-fight-for-access-to-medical-data-its-a-matter-of-life-and-death>

[779] Nursing Board Malaysia, *Code of Professional Conduct for Nurses* (1998)

[780] Ibid 2.

Why this concept has not reached the doctors' counterparts such as the MMC that is responsible for doctor's registration and conduct is unclear but probably lies in some of the arguments around medical paternalism, professional hierarchies and lack of awareness.

Drawing from the UK experience in which there has been a shift in the balance of power for greater involvement of patients in healthcare,[781] the publication of 'The impact of patient and public involvement on UK NHS healthcare: a systematic review',[782] involving patients and the public healthcare communities are set to ensure that the voices of the patients, their carers and the public are listened to at every level of the service. The key elements are to encourage empowerment and knowledge, behavioural skills and self-responsibility. Black states that lack of knowledge is an important element of regulatory failure and persuasion through patient and medical education can often provide a way to bring the doctor-patient relationship to a well-rounded view of the decision at hand and the issues at stake.[783] Education is the basis of progress in every society and family[784] and as an advocate, persuasive and credible information in healthcare can improve people's abilities to meet their own or their peers' needs and mobilise the resources to take control of their lives. It may be as simple as providing a brochure with information on their right to access medical records.

An advocacy policy can also be created to cover the right of patients to access medical records and highlight the responsibility of a certain group of patients to the service such as a patient advocacy and liaison office in the local hospital. Advocates can emphasise that patients who engage within their medical information have better outcomes such as 'better informed, more

[781] M Pearson and others, 'Involving Patients and the Public in Healthcare Operational Research—the Challenges and Opportunities' (2013) 2 Operations Research for Health Care 86.
[782] Carole Mockford and Sophie Staniszweska, 'The Impact of Patient and Public Involvement on Uk NHS Health Care: A Systematic Review' (2011) 24 International Journal for Quality in Health Care 28.
[783] Black, *Critical Reflections on Regulation*, 3.
[784] Kofi Annan, *If Information and Knowledge Are Central to Democracy, They Are Conditions for Development', Says Secretary-General UN Press* (press.un.org 1997).

engaged patient[s]; more mature doctor-patient relationship, shorter consultations, fewer errors and means of integrating services'.[785] Persuasive information focussing on patient rights, including that of access to medical records, can be in the form of education programmes that use technology or patient portals and conventional as well as social media. The same advocacy can also lobby the government for legislative reform.

As knowledge is a strong foundation for understanding and taking charge of one's health, this new responsibility can shift the dynamics of the doctor-patient relationship and tip the balance of power to support wider patient access using patient advocacy.

### 8.3.2 Recommendation 7: Nurturing partnership and collaboration in the doctor and patient relationship during information transmission

In Chapter 4, the concept of building a mutually beneficial partnership between healthcare providers and patients to improve patient-centred outcomes was discussed.[786] To forge this partnership, the MoH needs to place more emphasis on the collaboration culture that can bridge the gap in the doctor-patient relationship. Doctors and patients are the stakeholders at the bottom of the pyramid who can shift towards a more decentralised approach to leverage the regulation from a lower hierarchical but broader base.

As patients and doctors have discordant views on how access to medical records might change care, it is important to interpret these views correctly, provide support and develop a strategy for future healthcare. I have debated whether patients should be the co-owners of their medical records. Information transmission is influenced by many factors including perceived harm by the doctors, inability to understand medical terms and fiduciary duties. By doctors educating

785 Davies, 'Should Patient Be Able to Control Their Own Records?', 24.
786 *Patient-Centred Care*.

patients and vice-versa, both will have a more active role in the care and develop better understanding and trust.

Trust is crucial and Part two of the thesis explored and examined how trust and autonomy interact (see Section 6.3). Part of honouring patient autonomy is making sure patients have access to the information they need to participate in SDM. There appears to be a recognition that the current approach is only by relaying verbal information. Therefore, it is not unexpected that both patients and doctors appreciate the idea of providing more (or more accessible) information to patients. Widening patient access to records could be one of these interventions, be it in providing the base of information for the patient's condition before further discussions or in providing the impetus to develop the trust between the doctor and patient.

In Malaysia, the regulatory impediments to practices that empower patients are usually products of hierarchical structures and patriarchal patterns that frame the doctor-patient relationship. Although no intentional fault of the medical profession, the major obstacle relating to patient access is the notion that the request is to seek malpractice or support litigation. There are similarities between the role of doctors and patients in seeking access that is relevant to clinical decisions. Patients thereby gain knowledge by using this collaboration while encountering information included in medical records. Perhaps, like a parent reading a book to their child, doctors could facilitate the information in the medical records in the same manner, increasing the patient's understanding, potentially clarifying any fears but also finding out the parts which concern the patient the most and thus encourage SDM. This applies all three principles of beneficence, non-maleficence and autonomy concurrently in one setting. Nurturing this practice develops mutual trust and respect and potentially eliminates the question of ownership as it is indeed a true co-ownership of the medical records.

Since patients today are more educated, the awareness of the right to information should be enhanced by educating them through an awareness campaign using multiple means such as online educational websites, flyers distribution, self-management workshops and being explicitly informed of their rights. Some doctors may find this threatening, resulting in a defensive stance. However, social scientists Baarts and Tulinius describe a call for technological or training methods that would allow doctors-in-training to experience patienthood and bodily empathy.[787] I propose that would result in a more emphatic viewpoint, leading to improved doctor-patient partnership and trust. Widening patient access is the logical follow-on to such a partnership and subsequently to SDM. This in turn could transform the practice with a bottom-up approach, imparting behavioural changes to doctors' practices by changing the moral attitude towards their behaviour without necessarily relying on formal law alone. It could be a catalyst for a more intrinsic change to improve access to medical records.

## 8.4 Conclusion

Patients in Malaysia still lack advocacy and voice, a situation exacerbated by regulatory bodies that inhibit the patients' right to access their medical records. That is not to say that an explicit law on the matter could not be symbolic to enforce an idea on a group of individuals with self-interest. For example, a law that explicitly recognises patients' right to access medical records might symbolise a move towards patient-centredness and autonomy, despite the prevailing culture of medical paternalism. Laws can express values and are loaded with ethical dimensions: right or wrong by no means equal morality. However, Bilz and Nadler conclude that morally motivated individuals will, 'behave and believe as they do, almost no matter what

[787] Charlotte Baarts, Charlolotte Tulinius and Susanne Reventlow, 'Reflexivity - a Strategy for a Patient-Centred Approach in General Practice' (2000) 17 Family Practice 430, 433.

the law tells or demands of them'.[788] The effect of the law changing people's willingness to engage in regulated behaviour but there is no guarantee that this influences attitudes to a certain practice.[789] The law will force doctors to grant patients access whether they agree or not but in the long run it can be a source of guidance on morality. This is especially important in the medical community where a specific regulation is often perceived as undermining the identity and status of the profession. Underpinning the mechanism of influence is the credibility of the influencer themselves, in which success in influencing often falls on the influencer being morally correct and benefiting both parties. Doctors must believe that the practice, legislation or regulation will not erode their professional autonomy but instead create a mutually beneficial situation for all parties. The law thus can act as a nudge[790] in which doctors and healthcare providers will make a particular choice or behave in a particular way that is triggered by the regulatory environment and constitute a regulatory lever which the state can use to achieve its goals. For example, the state can enlist or incentivise others to act in ways that are consistent with regulatory goals like patient empowerment.

Drawing from the UK experience in which the DPA and AHRA provide the basis for determining the right of patients to access medical records, I have recommended the same for Malaysia. However, creating this new legislation but failing to reform basic professional self-regulation of individuals and reforming the regulatory bodies and enforcement, as is well-established in the UK, would be inadequate to change the overall behaviour skills and self-responsibility to enable wider access. Given that the MMC Guidelines are not legally binding and only apply to public and government hospitals, a single standard law accompanied by a guideline such as the Code of Practice might be the simplest solution. However, given the

[788] Bilz and Nadler, 'Law, Moral, Attitudes and Behavioral Change', 260.
[789] Ibid 241.
[790] Jakub M. Krawiec and others, 'Tools for Public Health Policy: Nudges and Boosts as Active Support of the Law in Special Situations Such as the Covid-19 Pandemic' (2021) 17 Globalisation and Health .

importance of shifting the general attitude towards a more patient-centred approach and the future development in implementing HIS and EMR involving multiple current and new actors, enacting new legislation will not provide the kind of oversight and guidance required. Despite legal compulsion resulting in a more immediate increase in compliance to provide patients with access and insights from the experience of regulation in the UK, the shift of mindset that the stakeholders required to ensure that there is legitimacy to a law enacted to create a more effective regulatory framework in Malaysia is lacking.

The proposed hybrid legal and non-legal approach is key to overcoming the regulatory challenges in Malaysia as a viable strategy to improve patient access as ethically justified and thus accepted by all stakeholders as the right course of action. Patient access in Malaysia is an area that will benefit from legal reform but is best configured around an awareness of the regulatory space in which the reforms take place, and the law can harness actors and resources to achieve the policy goals. How those legal reforms can be augmented with non-legal measures is something that requires more study and could become an agenda for future research. According to Professor Sir Ian Kennedy:

> 'Whatever moral view is adopted, regulation is called for and that law must be the appropriate mechanism [...] Law, as a mechanism for social regulation, if it is to command respect (and therefore) obedience, must not stray too far from the collective conscience of society'.[791]

[791] Ian Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press 1991).

# Chapter 9. Summary and conclusions

Over the years, as a practising clinician with clinical experience both in Ireland and Malaysia, I have developed a keen interest in clinical ethics. In the process, I have always struggled to understand the conundrum to grant patient access to medical records in Malaysia as an aspiring liberal and progressive country. This has prompted me to consider patient access to medical records in Malaysia as a topic for my PhD thesis. I have attempted to uncover different legal, ethical and regulatory dimensions to understand the current practice but also the justification and potential to widen patient access.

## 9.1 Summary

To address my research question, three sub-questions were formulated, with the deliberation taking up one part each. In Part 1, 'Medical Records and Their Regulation', I discussed the roles of medical records, the legal impediments to enabling wider access to records in Malaysia and offered a legal comparison between Malaysia and the UK. In Part 2, 'Ethical Analysis', I explored the ethical theories involved and the subsequent application which justifies the need to widen patient access to information in medical records using themes in everyday healthcare practice and the patient-doctor relationship. Part 3, 'Regulatory Challenges and Recommendations', proposed the legal and regulatory changes required to support the ethical necessity for improved access.

In Chapter 1 I provided a deliberation of the physics and metaphysics of medical records, covering primary and non-primary functions in society. I introduced the different types of records and their physical characteristics and their purpose as a tool to provide medical documentation of an individual's healthcare journey. I also discussed the roles followed by a

deliberation of the conceptual functions which fashioned medical records from their original physical format into a potential 'body politic' in a healthcare system. I illustrated medical records playing a biopolitical role in their design and their generative and versatile function which facilitates governmentality and particular social system of communication. This chapter was important in establishing medical records as a source of information and knowledge that when accessed appropriately, can embody multiple productive benefits that are highly relevant, both analytically and politically, in improving healthcare and its provision.

The chapter also examined how some Malaysian institutions have successfully introduced EMR, albeit through a system that is still restricted to healthcare providers and not to patients. Considering the limitations of the EMR including privacy and confidentiality concerns, security breaches, system implementation and operation, the chapter reviewed and concluded that the introduction of EMR as an important technology can be a platform to widen patient access to medical records. However, I emphasised that implementing EMR is only a partial solution to improving access for patients as the real problem lies in the lack of defined legal right on patient access to medical records in Malaysia.

Chapter 2 discussed the regulations and the legal impediments to widening access. I examined the Malaysian legal system including the Federal Constitution concerning medical records. The separation of powers between legislative, judicial and executive authorities and the constitutional distribution of power between federal and state governments were also reviewed. I also studied the legal jurisdiction and administration in Malaysia to provide context.

Chapter 2 also gave an overview of the Malaysian healthcare system, a dual-tier system consisting of both public and private sectors. Although the MoH is the internal regulator of the public sector, the private sector is regulated under the PHFSA, a significant incongruity which affects the entire regulatory system and the rules set out by authority bodies such as the MMC.

The Malaysian guidelines comprising the Good Medical Practice 2019 and the Guideline of Medical Records and Medical Reports 2006 as well as the Professional Conduct 2019 by the MMC state that a patient is entitled to have access to their own medical records, with the right of access recognised by the High Court in *Nurul Husna*.[792] Despite endorsement from the professional authority and the judiciary, the normal practice is to refuse the patient's request unless ordered by the court. Therefore, there is a regulatory failure that has led to the routine practice of accessing medical records using legal avenues. Bodies such as the MMC should have a strong influence on doctors' practices and provide guidance for what constitutes acceptable practice. However, the MMC's guidance is not legally binding and cannot be enforced. Denial of patients' right of access to their medical records is considered a breach of practice as per the MMC Guidelines but is not subjected to disciplinary sanctions which cause further rifts in the doctor-patient relationship and promotes defensive practices due to fear of litigation, as medical records are commonly obtained for the purpose of the latter. One of the other main factors that impede widening patient access is that current guidelines seem to favour doctors and hospitals, wherein patient access requires permission from a higher authority such as the hospital's Director, thus resulting in patients having to request their medical records through a court order. This chapter also highlighted the existence of an imbalance of power between doctors and patients, which may reflect the lack of underlying respect for patients and their autonomy. Although it is theoretically correct to consider medical records as part of data privacy, the Malaysian Personal Data Protection law, unlike its UK counterpart, has yet to recognise a general right to access medical records in the healthcare sector.

Chapter 3 examines UK legislation regarding access to medical records. The UK was selected for comparison as Malaysia draws heavily on English law. The UK's approach to medical records seems to have undergone a process of maturity. Therefore, the similarity in common

[792] *Nurul Husna Muhammad Hafiz & Anor v Kerajaan Malaysia & Ors*.

law and having experienced the process of continuous improvements made the UK an ideal comparator. The UK, as a developed country with established legislation and prior engagements on this topic, was best placed to be exemplified not only for its development in the matter but to illuminate and identify the unique challenges that Malaysia will face in addressing this issue.

The chapter also introduced the English common law on recognition of patient access and the evolution of the legislation which was later further developed in line with technology and technological advancements. The UK's DPA 2018 is likely to be considered as a statutory model to be adopted in Malaysia, and so a comparative analysis was performed to further enrich the discussion on whether Malaysia should follow the UK's example. This chapter thus formed the basis on which I argued that legislation similar to the UK should be adopted as part of a strategy to improve and provide legal protection for patient access to their medical records in Malaysia.

The UK has more clearly defined statutory right in relation to patient access. However, widening patient access in Malaysia is not a straightforward question that can be answered simply by looking at other successful legislation and law such as in the UK. In a society such as Malaysia where there are complexities ranging from the new but emerging concept of patient autonomy in the doctor-patient relationship to the binary practice and regulation between the public and private sectors, ambiguity will persist unless clarity is provided, especially on the issue of 'ownership'. Thus, while it would be prudent to regulate Malaysia through legislation passed by the legislative body, this alone would likely be insufficient to change the attitude of either patients or doctors. For a right to be exercised successfully, it must be controlled in accordance with Malaysian principles as doctors in Malaysia inherently and traditionally assume the authoritative role in line with the Malaysian government and its health institutions that enforce state-centric governance. This comparison provided a background of different

values and expectations from different actors and an acknowledgement that legislation could directly achieve the goal.

In Part Two: Ethical Analysis, I turned to ethical theories to delineate my arguments and justify widening patient access. Chapter 4 introduced the main ethical theories proposed for medical practice, including the theoretical application of each theory in everyday clinical practice. I attempted to also outline the advantages and disadvantages of each theory. In Chapter 5, using Chapter 4 as a framework, the application of principlism on information transmission in the doctor-patient relationship as the main ethical approach with an emphasis on autonomy, beneficence and non-maleficence was discussed. Due to the conflicting values of these ethical principles which reflect the competing interests that occur in the doctor-patient relationship, the ethical theories were discussed under different themes based on the perspective of the patients, the doctors or both. To capture the essence of principlism necessitates an explanation of its history and the processes by which principlism takes effect which includes specification and balancing.

I also included the important concept of information transmission in the doctor-patient relationship which includes themes such as informed consent and doctors as communication providers, using illustrations and analogies to answer the research question on the essence of information provision in the form of medical records. It illustrates everyday ethical applications relevant to justifying patient access and acts as a preamble for future discussion. Respect for autonomy is an important element to justify legal requirements and recognition of patients' right to information. Informed consent can also be used to argue in favour of allowing access to medical records, as this allows the patient to be more informed to make better decisions. With informed consent in which comprehensive information is required, I also emphasised promoting respect for autonomy by discussing the doctor's duty to advise and their role as an information provider. Inextricably linked to respect for autonomy is beneficence, in which I

discussed patient-centred care and patient empowerment to project positive outcomes from the patient's perspective if patient access is widened. However, I also elaborated on the doctor's perspective using the principle of non-maleficence that drives the prevailing practice of medical paternalism and therapeutic privilege in Malaysia. As demonstrated throughout the chapter, ethical principles, primarily respect for autonomy, were applied to justify the necessity and acknowledge patients' right to information versus minimising potential harm. Weighing the benefits and harms of gaining information via wider access to patient records was exercised in a balancing act described in this chapter using respect for autonomy versus non-maleficence.

Chapter 6 addressed the main research question of whether Malaysia should widen patient access. The approach to specify which ethical theories should be applied to answer this question was considered in Chapter 4 and 5 and concluded with three main statements. The utilitarian approach justified wider patient access by maximising benefits using empirical evidence. The deontological approach suggested that restricting medical records is wrong and therefore, Malaysia should widen patient access. The principlist approach was used to discuss both sides of the argument from the patient's and the doctor's perspectives. After deliberating about the conflict between the ethical principles – autonomy and beneficence versus non-maleficence – I have recommended that respecting patient autonomy outweighed the other principles, which is in line with the central tenet in bioethics. This has even been enshrined and rationalised as an established legal entity with informed consent being the prime example of patient autonomy as a legal necessity. As a result, and through the ethical lens, I concluded that Malaysia should widen patient access.

In Part Three: Regulatory Challenges and Recommendations, I examined the legal and regulatory changes and their importance as part of a holistic approach to patient access. Having discussed the ethical issues, Chapter 7 proposed strategies to help reform and align the ethical and legal reasons to widen patient access by understanding how the two actors interact within

the complex regulatory space in Malaysia. Previously, I observed how lawmakers in Malaysia failed to protect patients' right to access resulting in unnecessary recourse to legal remedies. I mapped out the regulatory space discussed in Chapter 2 to illustrate the regulatory challenges that the actors and authorities faced.

After concluding that access to medical records should be widened for patients, I went on to consider how this might be done in practice and offered regulatory and social recommendations and provisions that respect both patients' and doctors' interests. In Chapter 7, I examined the advantages and limitations of legislation as the main solution to achieve this goal. The overall contribution was that the social-historical context in which a doctor-patient relationship occurs in Malaysia is still paternalistic and doctor-centric, as evident in the current practices which breach the guidelines that acknowledge patients' right to access. Therefore, what Malaysia requires is a set of legal and regulatory changes which I have proposed in Chapter 8. I argued that the changes in practice require an improvement that can only prevail if there is resilience in the overall system to include a moral compulsion that drives the change in practice. Introducing and improving legislation like the UK model, reinforcing and tightening regulation with consistency and universality across both public and private sectors, implementing EHR and focussing on holistic practice such as promoting advocacy and information transmission through partnership and collaboration were recommended to deliver an approach that can improve patient access. I proposed that these recommendations serve as a more robust method of changing not only compliance with good practice, but also fundamentally shifting the healthcare system to support concepts such as patient autonomy and empowerment.

## 9.2 Conclusion

According to Majone,[793] expertise has always been a crucial source of regulatory legitimisation because regulation is reliant on scientific knowledge. In my thesis, I have proposed that the regulatory failure in Malaysia leading to the current practice in which patient access is restricted is likely due to the lack of knowledge and information on the ethical principles and rights of patients to information. It is the purpose of this thesis to contribute to this scientific knowledge by examining the current practice of patient access. I have discovered that the generative and versatile roles of medical records, when accessed appropriately, can provide the basis of knowledge, and facilitate its own self-regulation using the concept of decentred regulation (see Chapter 7). As a theoretical but potential resource to produce a better map of the regulatory domain, access to the wealth of information in medical records can potentially create multiple benefits including formal laws, self-regulation, new agencies and advocacies, as well as empower patients.

The comparative analysis with the UK is important and has allowed me to translate the need to adopt legislation that is well-established and proven in another country, but especially to provide the legal protection and consistency that is lacking in Malaysia. While legalisation can interfere with autonomy and disempower certain groups (in this case, the doctors), I argue that it promotes the rights of patients and society. I discussed the concepts of regulatory failure and attempted to map out the regulatory space in Malaysia that portrayed the elements of the fragmentation of power and knowledge and lack of autonomy as causes of this regulatory failure under a state-centric government. While the comparative analysis in the UK indicates that legislation can help, the social-historical environment in Malaysia in which the doctor-

[793] Majone, 'From the Positive of the Regulatory State: Causes and Consequences of Changes in the Mode of Governance', 157.

patient relationship exists is still very paternalistic as evident from the guidelines and practice on this issue. Therefore, I argue that a change in practice can only prevail if there is buy-in from the whole system and both centralised and decentralised reforms are undertaken. With improved legislation, I also argue that doctors and healthcare institutions that are currently the owners of medical records should be protected in their intellectual property rights. Patients as the providers and receivers of information should also be protected over privacy and potential harm from the information and be given an established status within the system.

I also emphasised that legislation is not a 'cure-all' solution. As Gunnighnam argues, 'the use of multiple rather than single policy instruments and a broader range of regulatory actors, will produce better regulation.[794] As institutions in Malaysia are more likely to be state-controlled, the strategy to decentralise regulation could precipitate policy reform. Besides providing a comprehensive and up-to-date analysis of whether Malaysia should widen patient access, I have also explored the current regulatory limitations and inconsistencies in the healthcare system. I explored why the regulatory space poses challenges in Malaysia and thus legislation should not only be the solution. I proposed introducing a fiduciary duty as an experimental approach that is more compatible with the current imbalance of power in the doctor-patient relationship in Malaysia. The broader issues including fiduciary duties and increasing patient advocacy can also be translated to other matters.

In this thesis, I have offered an original contribution to the current literature. In Part One, the thesis examined, for the first time, the current Malaysian law, regulation and practice and compared them with those of the United Kingdom. Despite the existence of some lawfulness of this issue in Malaysia as demonstrated by the case laws, the practice of providing patient access to their medical records remains restricted. In Part Two, using the balancing act of

[794] Gunningham and Sinclair, 'Smart Regulation', 133.

principlism, I applied a well-known method to provide a novel perspective in which I used principlism to justify patient access to their own medical records. I also considered different methods using three ethical theories and proved that ethical solutions can work together. Analogy themes on information transmission in a doctor-patient relationship were discussed as relevant to the need for both ethical and legal necessity already established in informed consent to justify patient access to medical records. I hope that this original approach resonates with doctors and healthcare providers and help them to understand that granting access helps their current practice and fits with the values of healthcare practice, i.e. to provide vital and adequate information to patients in a truthful and trustworthy manner so the patients can make the best informed decision about their own health.

Subsequently, having explored the ethical lens and arguing that Malaysia should widen patient access to medical records, I then investigated how Malaysia could widen patient access in the local setting by understanding its regulatory space. In an innovative approach, I used Black's work[795] to explore a new perspective on this discussion, providing further clarity on the complexity that regulates this practice in Malaysia. Subsequently, in Chapter 8, I proposed that non-state and state recommendations as legal mandates can alter how a practice is developed but may not, in the long run, influence the attitudes of the stakeholders. This provides an opportunity for Malaysia whereby patient-centred care and autonomy should be more accepted and become the norm.

With the novel contributions of using ethical solutions and exploring the regulatory space to shed light in this topic, this PhD thesis will make an impact from both ends; with an originality and contribution of knowledge which will, in the short- to immediate-term, help increase

[795] Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World'

awareness, and in the long-term provide a unique solution and roadmap to influence the practice of patient access to medical records, as well as other ethical issues in Malaysia.

The conclusions and recommendations offer a fresh and holistic strategy to reform the paradigm of values and beliefs in granting patients wider access to their medical records as an ethically justified practice. This is where I believe the novelty and strength of this thesis lie. It would not be too much of a stretch to propose that the same approach that uses ethical arguments could be applied to other difficult topics involving information transmission and the doctor-patient relationship in Malaysia. This approach could be used to improve clinical practice as part of the vision towards a more progressive and patient-centred healthcare.

# Bibliography

**Journal Articles**


Abramson M, 'Autonomy Vs. Paternalistic Beneficence: Practice Strategies' (1989) 70 The Journal of Contemporary Social work

Alameddin M and others, 'Physicians' Perspective on Shared Decision-Making in Dubai: A Cross-Sectional Study' (2020) 18 Human Resources for Health 2

Aldosari B, 'Patients' Safety in the Era of EMR/EHR Automation' (2017) 9 Informatics in Medicine Unlocked 230

Alotaibi YK and Federico F, 'The Impact of Health Information Technology on Patient Safety' (2018) 38 Saudi Medical Journal 1173

Altman JH and others, 'Patients Who Read Their Hospital Charts' (1980) 302 New England Journal of Medicine 169

Altukistani A and others, 'Patient Portal Functionalities and Patient Outcomes among Patients with Diabetes: Systematic Review' (2020) 22 Journal of Medical Internet Research

Amer AB, 'Understanding the Ethical Theories in Medical Practice' (2019) 9 Open Journal of Nursing 188

Ammenwerth E, Schnell-Inderst P and Hoerbst A, 'The Impact of Electronic Patient Portals on Patient Care: A Systematic Review of Controlled Trials' (2012) 14 Journal of Medical Internet Research e162

Antoci A, Maccioni AF and Russu P, 'The Ecology of Defensive Medicine and Malpractice Litigation' (2016) 11 PLOS One e0150523

Appelbaum PS, 'Assessing of Patients' Competence to Consent to Treatment' (2007) 357 The New England Journal of Medicine 1834

Arvinder-Singh H and Abdul Rashid, 'The Intention to Disclose Medical Errors among Doctors in a Referral Hospital in North Malaysia' (2017) 18 BMC Medical Ethics 1

Aujoulat I, d'Hoore W and Deccache A, 'Patient Empowerment in Theory and Practice: Polysemy or Cacophony?' (2007) 66 Patient Education and Counseling 13

Austad T, 'The Right Not to Know - Worthy of Preservation Any Longer? An Ethical Perspective' (1996) 50 Clinical Genetics 85

Azarpazhooh MR and others, 'Covid-19 Pandemic and Burden of Non-Communicable Diseases: An Ecological Study on Data of 185 Countries' (2020) 29 Journal Stroke Cerebrovascular Disease

Baarts C, Tulinius C and Reventlow S, 'Reflexivity - a Strategy for a Patient-Centred Approach in General Practice' (2000) 17 Family Practice 430

Baldry M and others, 'Giving Patients Their Own Records in General Practitioner: Experience of Patients and Staff' (1986) 292 British Medical Journal 596

Balestrieri PJ, 'Autonomy Versus Deontology' (2009) 18 International Journal of Obstetric Anesthesia 189

Bali A and others, 'Management of Medical Records: Facts and Figures for Surgeons' (2011) 10 Journal of Maxillofacial and Oral Surgery 199

Banerjee I and Anuar MK, 'The Promise and Pitfalls of Leapfrogging - the Malaysian Experience' (1999) 1 Asia Pacific Media Educator 133

Bardram JE and Houben S, 'Collaborative Affordances of Medical Records' (2017) 27 Computer Supported Cooperative Work 1

Barnett O, 'Computers in Medicine' (1990) 263 Journal of the American Medical Association 2631

Barsky A, ' A Conflict Resolution Approach to Teaching Ethical Decision Making: Bridging Conflicting Values.' (2008) 83 Journal of Jewish Communal Service 164

Baumgarten E, 'The Concept of Patient Autonomy' (1999) 2020 Medical Updates 1

Benditt TM, 'Liability for Failing to Rescue' (1982) 1 Law and Philosophy 391

Berg M and Bowker G, ' The Multiple Bodies of the Medical Record: Toward a Sociology of an Artifact' (1997) 38 The Sociological Quarterly 513

Berman AC and Chutka DS, 'Assessing Effective Physician-Patient Communication Skills: “Are You Listening to Me, Doc?”' (2016) 28 Korean Journal of Medical Education 243

Bernabe RD and others, 'The Fiduciary Obligation of the Physician-Researcher in Phase Iv Trials' (2014) 15 BMC Medical Ethics 1

Bernadt M, Gunning L and Quenstedt M, 'Patients’ Access to Their Own Psychiatric Records' (1991) 303 British Medical Journal 967

Bernhardt JH, 'Record Keeping - Key to Professional Accountability' (1978) 26 Occupational Health Nursing 22

Black J, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a “Post-Regulatory” World' (2001) 54 Current Legal Problems

Blendon RJ and others, 'Common Concerns Amid Diverse Systems: Health Care Experiences in Five Countries' (2003) 22 Health Affairs 106

Bouri N and Ravi S, 'Going Mobile: How Mobile Personal Health Records Can Improve Health Care During Emergencies' (2014) 2 JMIR mHealth and uHealth

Brall C, Back PS and Maeckelberghe E, 'Ethical Aspects of Digital Health from a Justice Point of View' (2019) 29 European Journal of Public Health 18

Britten N and others, 'Consultants' and Patients' Views About Patient Access to Their General Practice Records' (1991) 84 Journal of the Royal Society of Medicine 284

Brooks LA, Manias E and Bloomer MJ, 'Culturally Sensitive Communication in Healthcare: A Concept Analysis' (2019) 26 Australian College of Nursing 383

Burnum JF, 'The Misinformation Era: The Fall of the Medical Record' (1986) 110 Annals of Internal Medicine 482

Callahan D, 'A Moral Good, Not a Moral Obsession' (1984) 14 The Hastings Center Report 40

Campanella P and others, 'The Impact of Electronic Health Records on Healthcare Quality: A Systematic Review and Meta-Analysis' (2015) 26 European Journal of Public Health 60

Carman D and Britten N, 'Confidentiality of Medical Records the Patient's Perspective' (1995) 45 British Journal of General Practice 485

Cave E, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception' (2017) 46 Common Law World Review 140

Chee HL, 'Ownership, Control, and Contention: Challenges for the Future of Healthcare in Malaysia' (2008) 66 Social Science & Medicine 2145

Cimino JJ, Patel VL and Kushniruk AW, 'The Patient Clinical Information System (Patcis): Technical Solutions for and Experience with Giving Patients Access to Their Electronic Medical Records' (2002) 68 International Journal of Medical Informatics 113

Coggon J and Miola J, 'Autonomy, Liberty and Medical Decision-Making' (2011) 70 Cambridge Law Journal

Collins SA and others, 'Acute Care Patient Portals: A Qualitative Study of Stakeholder Perspectives on Current Practices' (2017) 24 Journal of the American Medical Informatics Association 9

D'Costa SN, Kuhn IL and Fritz Z, 'A Systematic Review of Patient Access to Medical Records in the Acute Setting: Practicalities, Perspectives and Ethical Consequences' (2020) 21 BMC Medical Ethics 1

Daruwalla Z and others, 'Patient Empowerment: The Role of Technology' (2019) 257 Studies in Health Technology and Informatics 70

Daud MH and others, 'The Empower-Sustain E-Health Intervention to Improve Patient Activation and Self-Management Behaviours among Individuals with Metabolic Syndrome in Primary Care: Study Protocol for a Pilot Randomised Controlled Trial' (2020) 21 BMC Open

Davies B, 'The Right Not to Know and the Obligation to Know' (2020) 46 Journal in Medical Ethics 300

Davies B and Parker J, 'Doctors as Appointed Fiduciaries: A Supplemental Model for Medical Decision-Making' (2022) 31 Cambridge Quarterly of Helthcare Ethics 22

Davies P, 'Should Patient Be Able to Control Their Own Records?' (2012) 345 British Medical Journal 24

Dawson A, 'The Future of Bioethics: Three Dogmas and a Cup of Hemlock' (2010) 24 Bioethics 218

Delbanco T and others, 'Open Notes: Doctors and Patients Signing On' (2010) 153 Annals of Intern Medicine 121

Demott DA, 'Relationship of Trust and Confidence in Workplace' (2015) 100 Cornell Law Review 1255

Dewar S and Finlayson B, 'Reforming the Gmc' (2001) 322 British Medical Journal 689

Dive L and Newson AJ, 'Reconceptualizing Autonomy for Bioethics' (2018) 28 Kennedy Institute of Ethics Journal 171

Drury M and others, 'Patients with Cancer Holding Their Own Records: A Randomised Controlled Trial' (2000) 50 British Journal of General Practice 105

Dworkin G, 'Paternalism' (1972) 56 The Monist 68

Edelstein L and others, 'Communication and Conflict Management Training for Clinical Bioethics Committee' (2009) HEC Forum

Edwin AK, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege - Is It Ever Justified?' (2008) 42 Ghana Medical Journal 156

El-Haddad C, Hegazi I and Hu W, 'Understanding Patient Expectations of Health Care: A Qualitative Study' (2020) 7 Journal of Patient Experience 1724

Elwyn G and others, 'Shared Decision Making: A Model for Clinical Practice' (2012) 27 Journal of General Internal Medicine 1361

Emanuel E and Emanuel LL, 'Four Models of the Physician-Patient Relationship' (1992) 267 The Journal of the American Medical Association 2221

Embong AR, 'Malaysia as a Multicultural Society' (2002) 12 Macalester International 37

Engelbrecht SF, 'Can Autonomy Be Limited- an Ethical and Legal Perspective in a South African Context' (2014) 32 Journal of Forensic Odonto-Somatology 34

Esch T and others, 'Engaging Patients through Open Notes: An Evaluation Using Mixed Method' (2016) British Medical Journal 1

Esquivel A and others, 'Improving the Effectiveness of Electronic Health Record-Based Referral Processes' (2012) 12 BMC Medical Informatics and Decision Making

Evans R, 'Electronic Health Records: Then, Now, and in the Future' (2016) 1 Yearbook of Medical Informatics 48

Fallberg L and Mackenney S, 'Patient Ombudsmen in Seven European Countries: An Effective Way to Implement Patients' Rights?' (2003) 10 European Journal of Health Law 343

Feenan D, 'Medical Records: Law, Paternalism and Harm' (1995) 29 Journal of the Royal College of Physicians of London 401

Feenan D, 'Common Law Access to Medical Records' (1996) 59 The Modern Law Review 101

Ferreira A and others, 'Why Facilitate Patient Access to Medical Records' (2007) Studies in Health Technology and Informatics 77

Fisher B and Britten N, 'Patient Access to Records: Expectations of Hospital Doctors and Experiences of Cancer Patients' (1993) 43 British Journal of General Practice 52

Fong Ha J and Longnecker N, 'Doctor-Patient Communication: A Review' (2010) 10 The Ochsner Journal 38

Fossa AJ, Bell SK and DesRoches C, 'Opennotes and Shared Decision Making: A Growing Practice in Clinical Transparency and How It Can Support Patient-Centered Care' (2018) 25 Journal of the American Medical Informatics Association 1153

Ghosh AK, Josh S and Ghosh A, 'Effective Patient-Physician Communication – a Concise Review' (2020) 68 Journal of the Association of Physicians of India 53

Giardina TD and others, 'Patient Access to Medical Records and Healthcare Outcomes: A Systematic Review' (2014) 21 Journal of the American Medical Informatics Association 737

Gibson CH, 'A Concept Analysis of Empowerment' (1991) 16 Journal of Advanced Nursing 354

Gillon R, 'Medical Ethics: Four Principles Plus Attention to Scope' (1994) 309 British Medical Journal 184

Gillon R, 'Ethics Needs Principles—Four Can Encompass the Rest—and Respect for Autonomy Should Be “First among Equals”' (2003) 29 Journal of Medical Ethics 307

Gillon R, 'Defending the Four Principles Approach as a Good Basis for Good Medical Practice and Therefore for Good Medical Ethics' (2015) 41 Journal of Medical Ethics 111

Gold M, 'Is Honesty Always the Best Policy? Ethical Aspects of Truth Telling' (2004) 34 Internal Medicine Journal 578

Goldzweig CL and others, 'Electronic Patient Portals: Evidence on Health Outcomes, Satisfaction, Efficiency, and Attitudes' (2013) 159 Annals of Internal Medicine 677

Grissinger M, 'Disrespectful Behavior in Health Care: Its Impact, Why It Arises and Persists, and How to Address It—Part 2' (2017) 42 Medication Errors 74

Grossman LV and others, 'Implementation of Acute Care Patient Portals: Recommendations on Utility and Use from Six Early Adopters' (2018) 25 Journal of the Americal Medical Informatics Association 370

Gupta P, 'Avoiding Litigation in Clinical Practice' (2019) 24 Journal Indian Association of Pediatric Surgeons 158

Gupta V and others, 'An Introduction to Biotechnology' (2016) 23 Basic and Applied Aspects of Biotechnology 1

Gusmano MK, Maschke KJ and Solomon MZ, 'Patient-Centered Care, Yes; Patients as Consumers, No' (2019) 38 Health Affairs 368

Haber JG, 'Patients, Agents and Informed Consent' (2013) 1 Journal of Law and Health 43

Hall DE, Prochazka AV and Fink AS, 'Informed Consent for Clinical Treatment' (2012) 184 Canadian Medical Association Journal 533

Hall MA and Schulman KA, 'Ownership of Medical Information' (2009) 301 The Journal of the American Medical Association 1282

Hambali S and Khodapanahander S, 'A Review of Medical Malpractice Issues in Malaysia under Tort Litigation System' (2014) 6 Global Journal of Health Science 76

Hamid NA and others, 'Erosion of the Concept of Constitutional Supremacy in Malaysia' (2019) 4 International Journal of Law, Government and Communication 27

Hannan A and Webber F, 'Towards a Partnership of Trust' (2007) 127 Studies in Health Technology and Informatics

Hardavella G and others, 'Tip Tops to Deal with Challenging Situations: Doctor–Patient Interactions' (2017) 13 Breathe 129

Hattori H and others, 'The Patient's Right to Information in Japan- Legal Rules and Doctor's Opinions' (1991) 32 Social Science and Medicine 1007

Henman P, 'Computer Technology - a Political Player in Social Policy Processes' (1997) 26 Journal of Social Policy 323

Hersh W, 'The Electronic Medical Record: Promises and Problems.' (1995) 46 The Journal of the American Society for Information Science 772

Ikhsan MI and Matah LJ, 'Enacting Freedom of Information Act in Malaysia: A Cost-Benefit Analysis' (2022) 7 Malaysian Journal of Social Sciences and Humanities 1

India VI and Radhika M, 'Hippocratic Oath: Losing Relevance in Today's World?' (2019) 61 Indian Journal of Psychiatry

Ismail I, 'Judicial Certainty and Creativity: An Evaluation of Stare Decisis' (2004) 8 Jurnal Undang-Undang dan Masyarakat 79

Ismail NI, 'Adoption of Hospital Information System (His) in Malaysian Public Hospitals' (2015) 172 Procedia - Social and Behavioral Sciences 336

Jaafar N and others, 'Malaysian Health Literacy: Scorecard Performance from a National Survey' (2021) 18 International Journal of Environmental Research and Public Health 5813

Jabour A, 'The Impact of Electronic Health Records on the Duration of Patients' Visits: Time and Motion Study' (2020) 8 Journal of Medical Internet Research Medical Informatics

Jahn Kassim PN, 'Medical Negligence Disputes in Malaysia:Resolving through Hazards of Litigation or through Community Responsibilities?' (2013) 7 International Journal of Humanities and Social Sciences 1757

Jahn Kassim PN, Alias F and Wan Muhammad R, 'The Growth of Patient Autonomy in Modern Medical Practice and the Defined Limitations under the Shari'ah ' (2014) 22 IIUM Law Journal 213

James JT, Eakins DJ and Scully RR, 'Informed Consent, Shared-Decision Making and a Reasonable Patient's Wishes Based on a Cross-Sectional, National Survey in the USA Using a Hypothetical Scenario' (2019) 9 BMJ Open 1

Kaldijan LC and others, 'Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees' (2007) 22 Journal of General Internal Medicine 988

Kambhampati S, 'Shared Decision-Making and Patient Empowerment in Preventive Cardiology' (2016) 18 Current Legal Problems

Kirby MD, 'A Patient's Right of Access to Medical Records' (1995) 12 Journal of Contemporary Health Law & Policy

Krawiec JM and others, 'Tools for Public Health Policy: Nudges and Boosts as Active Support of the Law in Special Situations Such as the Covid-19 Pandemic' (2021) 17 Globalisation and health

Kruse CS and others, 'Security Techniques for the Electronic Health Records' (2017) 41 Journal of Medical System 1

Lau D, 'Patient Empowerment- a Patient-Centred Approach to Improve Care' (2002) 8 Hong Kong Medical Journal 372

Layman EJ, 'Ethical Issues and the Electronic Health Record' (2020) 39 Health Care Management 150

Le Gallez I and others, '*Montgomery's* Legal and Practical Impact: A Systematic Review at 6 Years' (2022) 28 Journal of Evaluation in Clinical Practice 690

Lee A, '"*Bolam'* to '*Montgomery'* Is Result of Evolutionary Change of Medical Practice Towards Patient-Centred Care' (2017) 93 Postgraduate Medical Journal 46

Lee EH, Patel JP and Fortin 6th AH, 'Patient-Centric Medical Notes: Identifying Areas for Improvement in the Age of Open Medical Records' (2017) 100 Patient Education and Counseling 1608

Lee YK and Ng CJ, 'The State of Shared Decision Making in Malaysia' (2017) 123-124 Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 66

Lee YK and others, 'Shared Decision-Making in Malaysia: Legislation, Patient Involvement, Implementation and the Impact of Covid-19' (2022) 171 Z Evid Fortbild Qual Gesundhwes 89

Leydesdorff L, 'Luhmann Describe the Interaction between These Three Distinctions as 'Social Systems of Communication'' (2000) 17 Systems Research and Behavioural Science 273

Liddell K, Simon DA and Lucassen A, 'Patient Data Ownership: Who Owns Your Health?' (2021) 8 Journal of Law and Biosciences 1

Limb M, 'Patient Access to Medical Records: What Is Happening with the Rollout in England?' (2022) 379 British Medical Journal

Lindrige J, 'Principlism: When Values Conflict' (2017) 9 Journal of Paramedic Practice 1

Liou S, 'Electronic Medical Records: The Good and the Bad' (2014) 7 Quill & Scope 14

Lipworth W and others, 'Doctors on Status and Respect: A Qualitative Study' (2013) 10 Journal of Bioethical Inquiry 205

Lopez KD and others, 'Electronic Health Record Usability and Workload Changes over Time for Provider and Nursing Staff Following Transition to New EHR' (2021) 93 Applied Ergonomics 1

Ludwick D and Doucette J, 'Primary Care Physicians' Experience with Electronic Medical Records: Barriers to Implementation in a Fee-for- Service Environment' (2009) International Journal of Telemedicine and Applications 1

Lytvynenko AA, 'A Right of Access to Medical Records: The Contemporary Case Law of the European Court of Human Rights and the Jurisprudence of Germany' (2020) 6 Athens Journal of Law 103

Mack P, 'Utilitarian Ethics in Healthcare' (2004) 12 International Journal of The Computer, the Internet and Management

Mah HC, Muthupalaniappen L and Chong WW, 'Perceived Involvement and Preferences in Shared Decision-Making among Patients with Hypertension' (2016) 33 Family Practice 296

Majone G, 'From the Positive of the Regulatory State: Causes and Consequences of Changes in the Mode of Governance' (1997) 17 Journal of Public Policy

Mandal J, Ponnambath DK and Parija SC, 'Utilitarian and Deontological Ethics in Medicine' (2016) 6 Tropical Parasitology 5

Martin-Fumadóa C and others, 'Medico-Legal, Ethical and Deontological Considerations of Vaccination against Covid-19 in Healthcare Professionals' (2021) Medicina Clinica 79

Matthewman S, 'Michel Foucault, Technology, and Actor-Network Theory' (2013) 17 Society for Philosophy and Technology Quarterly Electronic Journal 274

McCarthy J, 'Principlism or Narrative Ethics: Must We Choose between Them?' (2003) 29 Medical Humanities 65

McGuire AL and others, 'Who Owns the Data in a Medical Information Commons?' (2019) 47 Journal Law of Medicine and Ethics 62

McLean KL and Card SE, 'Informed Consent Skills in Internal Medicine Residency: How Are Residents Taught, and What Do They Learn' (2004) 79 Academic Medicine 128

McMillan B and others, 'Primary Care Patient Records in the United Kingdom: Past, Present, and Future Research Priorities' (2018) 20 Journal of Medical Internet Research

Menachemi N and Collum TH, 'Benefits and Drawbacks of Electronic Health Record Systems' (2011) 4 Risk Management and Healthcare Policy 47

Mirsha SR and others, 'Not Just a Receiver: Understanding Patient Behaviour in the Hospital Environment' (2016) Proc SIGCHI Conf Hum Factor Computer System 3103

Mockford C and Staniszweska S, 'The Impact of Patient and Public Involvement on Uk NHS Health Care: A Systematic Review' (2011) 24 International Journal for Quality in Health Care 28

Mohamad TAH and Trakic A, 'The Reception of English Law in Malaysia and Development of the Malaysian Common Law' (2015) 44 Common Law World Review 123

Mohamed D, 'Discovery and Inspection of Documents under the Malaysian and English Civil Procedure: A Study on Cases against the Internet Service Providers' (2012) 6 Australian Journal of Basic and Applied Sciences 185

Mohamed Fadzil R, Abd Halim AH and Ariffin AA, 'Defensive Medicine as a Result of Medical Negligence: A Brief Overview' (2018) 2 UNTAG Law Review 70

Mohan J and Raja Yaacob R, 'The Malaysian Telehealth Flagship Application: A National Approach to Health Data Protection and Utilisation and Consumer Rights' (2004) 73 International Journal of Medical Informatics 217

Mohd Amin NA and Mat Yatin SF, 'Role of Medical Records Management Practice in Improving Decision Making in University Hospital' (2020) 10 International Journal of Academic Research in Business and Social Sciences 1160

Mohd Mokhtar MF, 'The Law and Challenges to Access Medical Records for Medical Negligence Claims in Malaysia' (2020) 26 Jurnal Undang-Undang dan Masyarakat 43

Mold F and others, 'Patients' Online Access to Their Electronic Health Records and Linked Online Services: A Systematic Review in Primary Care' (2015) 65 British Journal of General Practice 141

Mossaed S, Leonard K and Eysenbach G, 'Patient Preferences and Perspectives on Accessing Their Medical Records' (2015) 46 Journal of Medical Imaging and Radiation Sciences 205

Mulheron R, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis' (2017) 70 Current Legal Problems 149

Munir S and Boaden R, 'Patient Empowerment and the Electronic Health Record' (2001) 84 Studies in Health Technology and Informatics 663

Murgic L and others, 'Paternalism and Autonomy: Views of Patients and Providers in a Transitional (Post-Communist) Country' (2015) 16 BMC Medical Ethics 1

National Health Service in Scotland Management Executive, 'Access to Health Records Act 1990' (1991)

Ng CJ and others, 'An Overview of Patient Involvement in Healthcare Decision-Making: A Situational Analysis of the Malaysian Context' (2013) 13 BMC Health Services Research 1

Ngo E and others, 'The Importance of the Medical Record: A Critical Professional Responsibility' (2016) 31 Medical Practice Management 305

Nik Ariffin NA and others, 'Implementation of Electronic Medical Records in Developing Countries: Challenges & Barriers' (2018) 7 International Journal of Academic Research in Progressive Education and Development 187

Nsiah C, Siakwa M and Ninnoni JP, 'Registered Nurses' Description of Patient Advocacy in the Clinical Setting' (2019) 6 Nursing Open 1124

Ombrellaro MP, 'Access Control in an Electronic Medical Record System' (2007) Patent Application Publication

Panhwar MS and Kalra A, 'Breaking Down the Hierarchy of Medicine:The Airline Industry Has Taken the Lead to Improve Communications for Pilots, It Is Now Time for Medicine to Follow with Physicians' (2019) 40 European Heart Journal 1482

Papoutsi C and others, 'Patient and Public Views About the Security and Privacy of Electronic Health Records (EHRs) in the Uk: Results from a Mixed Methods Study' (2015) 15 BMC Medical Informatics and Decision Making 1

Pavlish C and others, 'The Nature of Ethical Conflicts and the Meaning of Moral Community in Oncology Practice' (2014) 41 Oncology Nursing Forum

Pearson M and others, 'Involving Patients and the Public in Healthcare Operational Research—the Challenges and Opportunities' (2013) 2 Operations Research for Health Care 86

Pennings G, 'Reproductive Tourism as Moral Pluralism in Motion' (2002) 28 Journal of Medical Ethics 337

Pinto S and others, 'Healthcare Technologies: An Ethical Discussion' (2018) 24 Britiah Journal of Healthcare Management

Pojman L, 'Theories of Equality: A Critical Analysis' (1995) 23 Behaviour and Philosophy 1

Pulvirenti M, McMillan J and Lawn S, 'Empowerment, Patient Centred Care and Self-Management' (2014) 17 Health Expectations 303

Quick O, 'Outing Medical Errors: Questions of Trust and Responsibility' (2006) 14 Medical Law Review 22

Quick O, 'Duties of Candour in Healthcare: The Truth, the Whole Truth, and Nothing but the Truth?' (2022) 30 Medical Law Review 324

Rauprich O, 'Common Morality: Comment on Beauchamp and Childress' (2008) 29 Theoretical Medicine & Bioethics 43

Raymond L, Pare G and Marchand M, 'Extended Use of Electronic Health Records by Primary Care Physicians: Does the Electronic Health Record Artefact Matter?' (2017) 25 Health Informatics Journal 71

Rhodes R, 'Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge' (1998) 23 Journal of Medicine and Philosophy 10

Richardson HS, 'Specifying Norms as a Way to Resolve Concrete Ethical Problems' (1990) 19 Philosophy and Public Affairs 279

Richardson HS, 'Specifying, Balancing, and Interpreting Bioethical Principles' (2000) 25 Journal of Medicine and Philosophy 285

Risse GB and Warner JH, 'Reconstructing Clinical Activities: Patient Records in Medical History' (1992) 5 Social History of Medicine 183

Roberts LW and Dyer AR, 'Confidentiality and Truth Telling' (2003) 1 The Journal of Lifelong Learning in Psychiatry 445

Rodger JJ, 'Luhmann's Theory of Psychic Systems and Communication in Social Work Practice' (2021) 22 Journal of Social Work

Rose N and Miller P, 'Political Power Beyond the State: Problematics of Government' (1992) 43 The British Journal of Sociology 173

Rose N, O'Malley P and Valverde M, 'Governmentality' (2006) 2 Annual Review of Law and Social Science 83

Rosenman H, 'Patients' Rights to Access Their Medical Records: An Argument for Uniform Recognition of a Right of Access in the United States and Australia' (1997) 21 Fordham International Law Journal 1550

Ross SE and Lin CT, 'The Effects of Promoting Patient Access to Medical Records: A Review' (2003) 10 Journal of the American Medical Informatics Association

Rudner M, 'The Structure of Government in the Colonial Federation of Malaya' (1976) 13 South East Asian Studies

Russell J and others, 'Recognizing Rhetoric in Health Care Policy Analysis' (2008) 13 Journal of Health Services Research & Policy 40

Salvatore D, Numerato D and Fattore G, 'Physicians' Professional Autonomy and Their Organizational Identification with Their Hospital' (2018) 18 BMC Health Services Research 1

Sarabdeen J and Mohamed Ishak MM, 'E-Health Data Privacy: How Far It Is Protected?' (2008) 1 Communications of the IBIMA 110

Savulescu J, Persson I and Wilkinson D, 'Utilitarianism and the Pandemic' (2020) 34 Bioethics 620

Say RE and Thomson R, 'The Importance of Patient Preferences in Treatment Decisions—Challenges for Doctors' (2003) 327 BMJ 542

Shea M, 'Principlism's Balancing Act: Why the Principles of Biomedical Ethics Need a Theory of the Good' (2020) 45 Journal of Medicine and Philosophy 441

Shekar V and Brennan PA, 'Duty of Candour and Keeping Patients Safe' (2020) 38 Surgery 637

Shenkin BN and Warner DC, 'Giving the Patient His Medical Record: A Proposal to Improve the System' (1973) 289 New England Journal of Medicine 688

Shuster E, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337 New England Journal of Medicine 1436

Siddiqui W and Sharp RR, 'Beyond the Belmont Report' (2021) 21 The American Journal of Bioethics

Sobczak K, Leoniuk K and Janaszczyk A, 'Delivering Bad News: Patient's Perspective' (2018) 12 Patient Preference and Adherance 2397

Spatz ES, Krumholz HM and Moulton BW, 'The New Era of Informed Consent: Getting to a Reasonable Patient Standard through Shared Decision Making' (2016) 315 The Journal of the American Medical Association 2063

Stewart RM and others, 'Transparent and Open Discussion of Errors Does Not Increase Malpractice Risk in Trauma Patients' (2006) 243 Annals of Surgery 645

Stewart WF and others, 'Bridging the Inferential Gap: The Electronic Health Record and Clinical Evidence' (2007) 26 Health Affairs

Stirrat G and Gill R, 'Autonomy in Medical Ethics after O'neill' (2005) 31 Journal in Medical Ethics 127

Street A, 'Artefacts of Not-Knowing: The Medical Record, the Diagnosis and the Production of Uncertainty in Papua New Guinean Biomedicine' (2011) 41 Social Studies of Science 815

Strong C, 'Specified Principlism: What Is It, and Does It Really Resolve Cases Better Than Casuistry?' (2000) 25 Journal of Medicine and Philosophy

Sullivan R, W Menapace LW and White RM, 'Truth-Telling and Patient Diagnoses' (2001) 27 Journal of Medical Ethics 192

Takala T, 'Genetic Moralism and Health' (2019) 28 Cambridge Quarterly of Helthcare Ethics 225

Tazzyman A and others(2019) 13 Regulation & Governance 593

Tengku Zainudin TNA, Abdul Rahim A and Rajamanickam R, 'Consent to Medical Treatment and the Autonomous Power of Adult Patients: The Malaysian Legal Position' (2015) 6 Mediterranean Journal of Social Sciences

Tew Y, 'On the Uneven Journey to Constitutional Redemption: The Malaysian Judiciary and Constitutional Politics' (2016) 25 Washington Internaltional Law Journal Association 673

Thimbleby H, 'Technology and the Future of Healthcare' (2013) 2 Journal of Public Health Research 160

Thomas M, '*Rogers v Whitaker* Lands on Malaysian Shores - Is There Now a Patient's Right to Know in Malaysia' (2009) Singapore Journal of Legal Studies 182

Tseng P-E and Wang Y-H, 'Deontological or Utilitarian? An Eternal Ethical Dilemma in Outbreak' (2021) 18 International Journal of Environmental Research and Public Health 1

Tufo HM and Speidel JJ, 'Problems with Medical Records' (1971) 9 Medical Care 509

Ucnik L, 'Ethics, Politics and the Transformative Possibilities of the Self in Hannah Arendt and Michel Foucault' (2018) 44 Philosophy and Social Criticism 200

Varden H, 'Kant and Lying to the Murderer at the Door. One More Time: Kant's Legal Philosophy and Lies to Murderers and Nazis' (2010) 41 Journal of Social Philosophy 403

Varkey B, 'Principles of Clinical Ethics and Their Application to Practice' (2021) 30 Medical Principles and Practice 17

Vayena E and others, 'Policy Implications of Big Data in the Health Sector' (2017) 96 Bulletin of the World Health Organisation 66

Vermeir P and others, 'The Patient Perspective on the Effects of Medical Record Accessibility' (2017) 72 Acta Clinical Belgica 186

Vogel L, 'Doctors Need Retraining to Keep up with Technological Change' (2018) 190 Canadian Medical Association Journal

Waitzkin H and others, 'The Informative Process in Medical Care: A Preliminary Report with Implications for Instructional Communication' (1978) 7 Instructional Science 385

Wakefield D and others, 'Patient Empowerment, What Does It Mean for Adults in the Advanced Stages of a Life-Limiting Illness: A Systematic Review Using Critical Interpretive Synthesis' (2018) 32 Palliative Medicine 1288

Walker T, 'What Principlism Misses' (2009) 35 Journal of Medical Ethics 229

Waller A and Alcantara O, 'Ownership of Health Information in the Information Age' (1998) 69 Journal of American Health Information Management Association 28

Walshe K, 'Medical Regulation: More Reforms Are Needed' (2014) 349 British Medical Journal

Wan Abdullah and Nik Rosnah, 'Medical Regulation in Malaysia: Towards and Effective Regulatory Regime' (2002) 21 Policy and Society 94

Wecth C, 'Patient Access to Medical Records: Yea or Nay?' (1978) 6 Legal Aspects of Medical Practice

Weinert C, 'Giving Doctors' Daily Progress Notes to Hospitalized Patients and Families to Improve Patient Experience' (2017) 32 American Journal of Medical Quality 58

Weiss GB, 'Paternalism Modernised' (1985) 11 Journal of medical Ethics

White SM, Deacy N and Sudan S, 'Trainee Anaesthetists' Attitues to Error, Safety and the Law' (2009) 26 European Journal Anaesthesiology 463

Wibe T and others, 'Lay People's Experiences with Reading Their Medical Record' (2011) 72 Social Science & Medicine

Williams F and Boren SA, 'The Role of the Electronic Medical Record (EMR) in Care Delivery Development in Developing Countries: A Systematic Review' (2008) 16 The Journal of Innovation in Health Informatics

Winkelman WJ and Rossos PG, 'Patient-Perceived Usefulness of Online Electronic Medical Records: Employing Grounded Theory in the Development of Information and Communication Technologies for Use by Patients Living with Chronic Illness' (2005) 12 Journal of the American Medical Informatics Association 306

Yang JS, Mamudu HM and Mackey TK, 'Governing Noncommunicable Diseases through Political Rationality and Technologies of Government: A Discourse Analysis' (2020) 17 International Journal of Environmental Research and Public Health

Yarmohammadian MH and others, 'Medical Record Information Disclosure Laws and Policies among Selected Countries; a Comparative Study' (2010) 15 Journal of Research in Medical Sciences 140

Zolkefli Y, 'Evaluating the Concept of Choice in Healthcare' (2017) 24 Malaysian Journal of Medical Sciences 92

Zolkefli Y, 'The Ethics of Truth-Telling in Health-Care Settings' (2018) 25 Malaysian Journal of Medical Sciences

Noordin SM and Supramaniam S, *Update: An Overview of Malaysian Legal System and Research* (Houser Global Law School Program, New York University School of Law 2016)

**Books**


Ayres I and Braithwaite J, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992)

Baldwin R, Scott C and Hood C, *A Reader on Regulation* (Oxford University Press 1998)

Beauchamp TL and Childress JF, *Principles of Biomedical Ethics* (5th edn, Oxford University Press 2001)

Beauchamp TL and Childress JF, *Principles of Biomedical Ethics* (7th edn, Oxford University Press 2013)

Becker LC and Becker CB, *Encyclopaedia of Ethics* (Routledge 2001)

Black J, *Critical Reflections on Regulation* (Centre for Analysis of Risk and Regulation at the London School of Economics and Political Science 2002)

Dick RS, Steen EB and Detmer DE, *The Computer-Based Patient Record: A Revised Edition: An Essential Technology for Health Care.* (Revised edn, National Academy Press 1997)

English V, *Medical Ethics Today: The Bma's Handbook of Ethics and Law* (2nd edn, 2004)

Faden RR and Beauchamp TL, *A History and Theory of Informed Consent* (Oxford University Press 1986)

Gartee R, *Electronic Health Records: Understanding and Using Computerised Medical Records* (Third edn, Pearson 2016)

George C and Whitehoyse D, *Ehealth: Legal, Ethical and Governance Challenges* (Springer 2013)

Hirschman AO, *The Rhetoric of Reaction: Perversity, Futility, Jeopardy* (The Belknap Press of Harvard University Press 1991)

Huffman EK, *Medical Record Management* (9th edn, Physicians' Record Company 1990)

Jaafar S and others, *Malaysia Health System Review* (Health Systems in Transition, WHO Regional Office for the Western Pacific 2012)

Jahn Kassim PN, *Law and Ethics Relating to Medical Profession* (International Law Book Services 2007)

Jahn Kassim PN, *Medical Negligence in Malaysia: Cases and Commentary* (Sweet and Maxwell Asia 2009)

Jomo KS and Wong SN, *Law, Institutions and Malaysian Economic Development* (University of Chicago Press 2008)

Kennedy I, *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press 1991)

Malaysia Medical Council, *Consent for Treatment of Patients by Registered Medical Practitioner* (2017)

Manson NC and O'Neil O, *Rethinking Informed Consent in Bioethics* (Cambridge University Press 2007)

Miller JS, *Utilitarianism* (Second edn, Longmans, Green and Co 1864)

Norris A, *Essentials of Telemedicine and Telecare* (John WIley & Sons, LTD 2001)

O'Neil O, *Autonomy and Trust in Bioethics* (Gifford Lecturers, Cambridge University Press 2002)

Omar H, *Law of Evidence in Malaysia* (Second Edition edn, Sweet & Maxwell 2018)

Palumbo R, *The Bright Side and the Dark Side of Patient Empowerment* (Springer 2017)

Rinaldi G, *New Perspectives in Medical Records: Meeting the Needs of Patients and Practitioners (Tele-Health)* (Springer 2017)

Rogers WA and Braunack-Mayer AJ, *Practical Ethics for General Practice* (Second edn, Oxford University Press 2009)

Ross D and Stratton-Lake P, *The Right and the Good* (Oxford University Press 2002)

Rubin EB, *Handbook of Clinical Neurology* (2013)

Schneider CE, *The Practice of Autonomy: Patients, Doctors and Medical Decisions* (Oxford University Press 1998)

Sellen A and Harper R, *The Myth of the Paperless Office* (The Mit Press, 2002)

Selznick P, *Focusing Organisational Research on Regulation* (Regulatory Policy and the Social Sciences, Univeristy of California Press 1985)

Thomson JT and Freudenberger KS, *Crafting Institutional Arrangements for Community Forestry:The Characteristics of the Rules and Resource Management Incentives* (1997)

Tranberg H and Rashbass J, *Medical Records Use and Abuse* (Radcliffe Medical Press 2004)

Wellman C, *Moral Consensus and the Law* (Dorrecht: Springer 2011)

Wood AW, *Kantian Ethics* (Cambridge University Press 2012)

**Book Sections**

Abdullah B, 'Impact of Teleradiology in Clinical Practice: A Malaysian Perspective' in Kumar S and Krupinski E (eds), *Teleradiology* (Springer 2008)

Baldwin R, Cave M and Lodge M, 'Introduction', *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press 2011)

Baldwin R, Cave M and Lodge M, 'Regulatory Failure', *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press 2011)

Baldwin R, Cave M and Lodge M, 'Self-Regulation, Meta-Regulation, and Regulatory Networks', *Understanding Regulation: Theory, Strategy, and Practice* (Second edn, Oxford University Press 2011)

Bilz K and Nadler J, 'Law, Moral, Attitudes and Behavioral Change' in Zamir E and Teichman D (eds), *The Oxford Handbook of Behavioural Economics and the Law* (Oxford University Press 2014)

Braithwaite J, 'Neoliberalism or Regulatory Capitalism?', *Regulatory Capitalism: How It Works, Ideas for Making It Work Better* (Edward Elgar 2008)

Brazier M and Lobjoit M, 'Fiduciary Relationship: An Ethical Approach and a Legal Concept? ' in Bennett R and Erin CA (eds), *Hiv and Aids : Testing, Screening, and Confidentiality (Issues in Biomedical Ethics)* (Oxford University Press 1999)

Dworkin G, 'The Nature of Autonomy', (Cambridge University Press 1988)

Gunningham N and Sinclair D, 'Smart Regulation', *Regulatory Theory* (ANU Press 2017)

Hancher L and Moran M, 'Organising Regulatory Space', *Capitalism, Culture and Economic Regulation* (Clarendon Press 1989)

Horton DP, 'Accountability and Time', *Mental Health Homocide and Society: Understanding Health Care Governance* (Hart Publishing 2019)

Jordana J and Levi-Faur D, 'Chapter 1 in the Politics of Regulation', *The Politics of Regulation in the Age of Governance* (Edward Elgar Publishing 2005)

Lee E, 'Limitations of the Personal Data Protection 4 Act 2010 and Personal Data Protection in Selected Sectors' in Ismail N, Cieh Y and Lee E (eds), *Beyond Data Protection : Strategic Case Studies and Practical Guidance* (2013th edn, Springer 2013)

**Newspaper Articles**

Farr C, 'Patient Advocates Fight for Access to Medical Data: 'It's a Matter of Life and Death"(<https://www.kqed.org/futureofyou/2519/patient-advocates-fight-for-access-to-medical-data-its-a-matter-of-life-and-death>

Shazwani I, 'Health Ministry Gets 7,000 Complaints, Spends Rm20mil on Compensation Annually' *New Straits Times* (<https://www.nst.com.my/news/nation/2017/11/299206/health-ministry-gets-7000-complaints-spends-rm20mil-compensation-annually>

Zainuddin A, 'Cases on Medical Negligence on the Rise, Health Ministry's Data Shows' *The Malaysian Reserve* (<https://themalaysianreserve.com/2019/09/18/cases-on-medical-negligence-on-the-rise-health-ministrys-data-shows/>

**Webpage**

Annan K, *If Information and Knowledge Are Central to Democracy, They Are Conditions for Development', Says Secretary-General Un Press* (press.un.org 1997)

Shah P and others, *Informed Consent* (StatPearls Publishing 2021)

Faculty of Medicine Universiti Teknologi MARA, *Master in Medical Ethics and Medical Jurisprudence* (Universiti Teknologi MARA 2016)

Facebook, *Campaign for Freedom of Information*

Academy of Medicine Malaysia, 'Ethical Professional Practice Guidelines' (2016)accessed 18 July 2022

Agency for Healthcare Research and Quality, 'Strategy 6h:Tools to Help Patients Communicate Their Needs' (2013) <www.ahrq.gov/cahps/quality-improvement/improvement-guide/6-strategies-for-improving/communication/strategy6htools.html> accessed 6 January 2021

American Medical Association, 'Guiding Principles for the Collection, Use, and Warehousing of Eelectronic Medical Records and Claims Data' (<www.ama-assn.org/apps/pf_new/pf_online> accessed 20 November 2019

American Medical Association, 'Records of Physician: Information and Patients' (2011) accessed 7 June 2021

British Medical Association, 'Access to Health Records' ((2018) <https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/access-to-health-records> accessed 22 June 2019

Care Information Exchange, 'How It Works' (<https://www.careinformationexchange-nwl.nhs.uk/how-it-works> accessed 10 June 2023

Cheverie J, 'Why Autonomy Is Important for Peak Performance?' (2015) accessed 26 September 2020

Crown Records Management, 'How to Store Physical Records' (2020) <https://www.crownrms.com/ae/insights/how-to-store-physical-records/> accessed 9 June 2019

Don R, 'How to Handle the Medico Legal Cases' (2017) <http://www.myhealth.gov.my/en/handle-medico-legal-cases/> accessed 13 Sept 2021

General Medical Council, 'Good Medical Practice - Ethical Guidance' (<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice> accessed 11 June 2023

Haynes L, 'Gps Demand End to Defensive Medicine Via 'No Fault' Compensation Scheme' (*GP Online - Haymarket Media Group Ltd,* 2022) <https://www.gponline.com/gps-demand-end-defensive-medicine-via-no-fault-compensation-scheme/article/1755705> accessed 7 July 2022

Health and Safety Executive, 'Who Regulates Health and Social Care' accessed 20 May 2019

Hospis Malaysia, 'Advocacy' (2018) accessed 15 November 2021

Index Murni, 'Malaysia Demographics Profile' ((2021) <https://www.indexmundi.com/malaysia/demographics_profile.html#:~:text=33%2C519%2C406%20(July%202021%20est.)&text=Bumiputera%2062.5%25%20(Malays%20and%20indigenous,9.8%25%20(2019%20est.)&text=The%20World%20Factbook%2C%20the%20indispensable%20source%20for%20basic%20information.> accessed 15 September 2022

Jason C, 'Ama Study Shows Poor EHR Usability Leads to Physician Burnout' (2019) <https://ehrintelligence.com/news/ama-study-shows-poor-ehr-usability-leads-to-physician-burnout> accessed 24 January 2020

Kasule OH, 'Medical Ethics from Maqasid Al Shari'at' (2005) accessed September 10 2020

Lender DJ, 'Subpoenas:Using Subpoenas to Obtain Evidence' (2013) accessed 13 August 2021

Malaysia Medical Association, 'Code of Medical Ethics ' (2001) accessed 5 May 2019

McCarty R, 'The Formula of Autonomy ' (2014) <https://myweb.ecu.edu/mccartyr/GW/FormulaOfAutonomy.asp> accessed 12 September 2020

McCormick TR, 'Principle of Bioethics' (2018) accessed 5 February 2021

Molis J, 'Types of Medical Record Filing Systems' (2018) <https://bizfluent.com/info-8690511-types-medical-record-filing-systems.html> accessed 8 March 2019

National Health Service, 'TPP (Systmone Hub)' accessed 8 June 2023

National Health Service, 'Involving People in Their Own Health and Care: Statutory Guidance for Clinical Commissioning Groups and NHS England' (2017) <https://www.england.nhs.uk/wp-content/uploads/2017/04/ppp-involving-people-health-care-guidance.pdf> accessed 1 February 2020

National Health Service, 'Access to Patient Records through the NHS App' (*National Health Service,* 2022) <https://transform.england.nhs.uk/information-governance/guidance/access-to-patient-records-through-the-nhs-app/> accessed 7 July 2023

National Health Service, 'The NHS Expert Patient Programme (NHS EPP) Where Next and Its Relevance for Other Health Care Systems' ((2018)accessed 10 May 2020

National Health Service University College London Hospitals, 'Mycare UCLH' (<https://www.uclh.nhs.uk/our-services/find-service/mycare-uclh> accessed 8 June 2023

National Institute for Health and Care Excellence (NICE), 'Shared Decision Making' (<https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making> accessed 1 February 2020

NHS England, 'House of Care – a Framework for Long Term Condition Care' (<https://www.england.nhs.uk/ourwork/clinical-policy/ltc/house-of-care/> accessed 15 November 2022

Nordin S and Keng L, 'An Overview of Malaysian Legal System and Research' (*Hauser Global Law School Program,* 2016)accessed 8 June 2019

Paparella G, 'Person-Centred Care in Europe: A Cross-Country Comparison of Health System Performance, Strategies and Structures' (*Picker Insitute Europe,* 2016) <https://www.basw.co.uk/system/files/resources/basw_100601-9_0.pdf> accessed 10 May 2020

Ravindran A, 'Malaysia's Health Advocacy Still at Infancy Stage: Experts' (2020) accessed 21 January 2022

Shahani SH, 'Overview of the Comparative Analysis' (2020)accessed 8 May 2022

Smart W, 'Lessons Learned Review of the Wannacry Ransomware Cyber Attack' (2018) <https://www.england.nhs.uk/wp-content/uploads/2018/02/lessons-learned-review-wannacry-ransomware-cyber-attack-cio-review.pdf> accessed 6 January 2020

The George Washington University, 'The Difference between Electronic and Paper Documents ' (<https://www2.seas.gwu.edu/~shmuel/WORK/Differences/Chapter%203%20-%20Sources.pdf> accessed 25 June 2019

The Robbins Collection, 'The Common Law and Civil Law Traditions' (2010) <https://www.law.berkeley.edu/wp-content/uploads/2017/11/CommonLawCivilLawTraditions.pdf> accessed 20 May 2021

The Scotsman, 'Patient Records 'Open to Prying Eyes'' (2010) <https://www.scotsman.com/health/patient-records-open-prying-eyes-2471207> accessed 5 July 2022

Tomlinson T, 'Balancing Principles in Beauchamp and Childress' (<https://www.bu.edu/wcp/Papers/Bioe/BioeToml.htm> accessed 6 March 2020

Tre LaRosa, 'Exploring Autonomy and Paternalism in the Doctor-Patient Relationship' (*Cystic Fibrosis News Today,* 2020) <https://cysticfibrosisnewstoday.com/columns/autonomy-paternalism-doctor-patient-communication/#:~:text=An%20abstract%20spectrum%20exists%20between,the%20patient%20loses%20all%20autonomy.> accessed 20 September 2020

UK parliament, 'Access to Health Records Bill' (1990) <https://api.parliament.uk/historic-hansard/commons/1990/feb/23/access-to-health-records-bill> accessed 20 January 2020

Universiti Malaya, 'Building Capacity and Partnerships for Health Advocacy' (*Universiti Malaya,* 2020) <https://um.edu.my/news/building-capacity-and-partnerships-for-health-advocacy> accessed 23 January 2021

World Health Organisation, 'Medical Records Manual: A Guide for Developing Countries' (2006) <http:www.wpro.who.int/publications/docs/MedicalRecordsManual> accessed 11 Oct 2022

World Health Organisation, 'The Conceptual Framework for the International Classification for Patient Safety' (2009) <https://onlinelibrary.wiley.com/doi/full/10.1111/jocn.13378> accessed 8 January 2020

World Medical Association, 'International Code of Medical Ethics' (1949) accessed 13 February 2021

World Medical Association, 'World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects' (2013) accessed 9 February 2021

Wrigley D, 'Call to Rethink Citizen Access Programme' (*British Medical Association,* 2022) <https://www.bma.org.uk/news-and-opinion/call-to-rethink-citizen-access-programme> accessed 27 February 2023

Yen OS, 'The Malaysian Personal Data Protectcon Act 2010: A Brief Overview' (2010) <http://www.taypartners.com.my/en/images/OurResources/Articles-LegalTaps/legaltaps-201008.pdf> accessed 23 May 2021

**Government Documents**

British Medical Association Guidance, *Gps as Data Controllers under the General Data Protection Regulation* (2018)

General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008)

General Medical Council, *The General Medical Council and Professional Standards Authority: Proposed Changes to Modernise and Reform the Adjudication of Fitness to Practise Cases* (2014)

General Medical Council, *Openness and Honesty When Things Go Wrong: The Professional Duty of Candour* (2015)

General Medical Council, *Confidentiality: Good Practice in Handling Patient Information* (2017)

General Medical Council, *Decision Making and Consent* (2020)

Health and Safety Executive, *Memorandum of Understanding between the Care Quality Commission and the Health and Safety Executive* (2017)

Information Commissioner's Office, *About the Ico*

Information Commissioner's Office, *Exemptions*

Information Commissioner's Office, *Guide to the General Data Protection Regulation*

Information Commissioner's Office, *An Overview of the Data Protection Act 2018*

Information Commissioner's Office, *Right of Access*

Information Commissioner's Office, *What Happens When Someone Complains*

Lord Chancellor and Secretary of State for Justice by Command of Her Majesty, *Government Response to the Justice Committee's Report: Post-Legislative Scrutiny of the Freedom of Information Act 2000* (2012)

Malaysian Medical Council, *Guideline of the Malaysian Medical Council - Medical Records and Medical Reports* (2006)

Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Confidentiality* (2011)

Malaysian Medical Council, *The Malaysian Medical Council Guidelines - Good Medical Practice* (2019)

Ministry of Health, *Electronic Medical Records* (2006)

Ministry of Health, *Jadual Pelupusan Rekod Perubatan Kementerian Kesihatan Malaysia* (2007)

Ministry of Health, *Guidelines for the Management of Patients' Medical Records for Hospitals and Medical Institutions* (2010)

Ministry of Health(2014)

Ministry of Health Malaysia, *Private Medical Practice Control* (Government of Malaysia)

Ministry of Health Malaysia, *Concept Request for Proposal for Lifetime Health Plan: Telemedicine Flagship Application* (Government of Malaysia 1997)

Ministry of Health Malaysia, *National Telehealth Policies: Telemedicine Flagship Application* (Government of Malaysia 2000)

Ministry of Health Malaysia, *Ministry of Health Official Website* (2010)

NHS Foundation Trust, *Consent to Examination or Treatment Policy* (2019)

Scottish Information Commissioner, *Foi Law in Scotland*

Yusuf ZA and Bhattasali D, *Economic Growth and Development in Malaysia: Policy Making and Leadership* (2008)

European Court of Human Rights, *Handbook on European Law Relating to Access to Justice* (Council of Europe 2016)

Nursing Board Malaysia, *Code of Professional Conduct for Nurses* (1998)

**Conference Papers**

Ismail NI and Abdullah NH, 'Developing Electronic Medical Records Framework for Malaysia's Public Hospitals' (IEEE Colloquium on Humanities, Science and Engineering)

Kadivar M, 'An Introduction to the Public and Private Debate in Islam' (Social Studies Conference)

Lim C and others, '"It Just Seems Outside My Health": How Patients with Chronic Conditions Perceive Communication Boundaries with Providers' (HHS Public Access)

Wilcox L and others, 'Designing Patient-Centric Information Displays for Hospitals' (Proceedings of the SIGCHI Conference on Human Factors in Computing Systems)

**Dictionaries**

'Advocacy'(Oxford University Press 2022)

'Advocate'(Oxford University Press 2018)

**Encylopedias**

*Autonomy in Moral and Political Philosophy* (2003)

*The Principle of Beneficence in Applied Ethics* (2008)

*The History of Utilitarianism* (2009)

*Principlism*

*Epicurus (341—271 B.C.E.)*

*Patient-Centred Care* (2019)

*Act and Rule Utilitarianism*

**Theses**

Griffiths S, 'Evaluating Health Care Record in Rheumatology' (University of Sheffield 1996)

Joyce P, ' Risk, Trust and Governmentality: Setting Priorities in the New NHS' (University of Salford 1999)

Kaur S, 'The Adequacy of the Ethics Review Process in Malaysia: Protection of the Interests of Mentally Incapacitated Adults Who Enrol in Clinical Trials' (University College London

Neog B, 'An Understanding of Common Morality' (University Utrecht 2007)

Reyes-IIllg G, 'Respect for Patient Autonomy in Veterinary Medicine: A Relational Approach' (Colorado State 2017)

Sulaiman H, 'Healthcare Information Systems Assimilation: The Malaysian Experience' (RMIT University 2011)

Yatim R, 'Freedom under Executive Power in Malaysia: A Study of Executive Supremacy' (King's College London 1994)

**Reports**

Berwick D, *A Promise to Learn - a Commitment to Act: Improving the Safety of Patients in England* (2013)

Canadian Health Infoway, *The Emerging Benefits of Electronic Medical Record Use in Community-Based Care* (2013)

Dalton D and Williams N, *Building a Culture of Candour* (2014)

Francis R, *The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Hc 898-111* (2013)

Friedberg MW and others, *Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy* (Rand Health Quarterly, 2013)

International Labour Organization, *Teleworking During the Covid-19 Pandemic and Beyond: A Practical Guide* (2020)

Jahn Kassim PN, *Medical Negligence Litigation in Malaysia: Current Trend and Proposals for Reform*)

Kulakiewicz A, Powell T and Parkin E, *Patient Health Records: Access, Sharing and Confidentiality* 07103 (2022)

Mata-Cervantes G, E Clay C and Baxter C, *Empowering Patients through Their Personal Health Record* (2016)

Ministry of Health, *E-Bulletin Medico Legal Section* (2022)

Parkin E, *The Care Quality Commission* (2020)

Parliament of UK, *Data Protection and Access to Personal Health Information* (1993)

Satyanarayana Rao K, *Informed Consent: An Ethical Obligation or Legal Compulsion* (Journal of Cutaneis Aesthetic Surgery, 2008)

Sekhar WY and others, *Palliative Care Needs Assessment Malaysia* (2016)

US Department of Health and Human Services, *The National Alliance for Health Information Technology Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information Technology Terms* (2008)

World Bank Report, *Court Backlog and Delay Reduction: A Poverty Reduction and Economic Management Sector Unit East Asia and Pacific Reg* (2011)

World Health Organisation and UNICEF, *Primary Health Care: Report of the International Conference on Primary Health Care* (1978)