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I. Introduction

The use of artificial intelligence (AI) extends across the broad spectrum of medical services: diagnoses, predictions of medical risks, treatment or surgery, the giving of medical information and advice, monitoring of patients and even hospital administration. It has been forecast that the global market for AI solutions in the healthcare sector will increase significantly from US $ 1 billion to more than US $ 34 billion by 2025.[1]

The more common usage of AI for hospitals and doctors in clinical practice thus far has been in medical diagnosis and the predictive analysis of diseases and health conditions. AI medical diagnosis is typically conducted through machine recognition of patterns from training data comprising information of the various diseases and symptoms, the medical records and data concerning the patient, and prior diagnoses. In supervised learning, data that has been labelled in advance is inputted into a machine learning algorithm to teach the computer to recognise, for example, a tumour. In contrast, in unsupervised learning, data is fed to a machine learning algorithm in order to find, for instance, a method to distinguish different body fluids from the inputted data.[2] Deep learning algorithms are currently used in radiography, mammography for breast cancer detection, magnetic resonance imaging (MRI) for brain tumours and for diagnosing neurological disorders, including Alzheimer's disease.

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[1] Tractica, 'Artificial Intelligence for Healthcare Applications', www.tractica.omdia.com/research/artificial-intelligence-for-healthcare-applications.

[2] Daniel Hashimoto , Guy Rosman , Daniela Rus and Ozanan Meireles, 'Artificial Intelligence in Surgery: Promises and Perils' (2018) 268 (1) Annals of Surgery 70.

AI predictive analysis is undertaken via big data analysis or data aggregated from the Internet of Things, sensors and/or medical equipment. Natural language processing may be employed in the analyses of electronic medical record (EMR) data comprising the doctors' personal notes and narrations of symptoms. AI has even been employed in end-of-life decision-making. At the Stanford Hospital, a mortality prediction (deep learning) tool was used to help palliative care professionals identify dying patients within a 3–12-month period and who were likely to benefit from palliative care services.[3]

Hospitals and healthcare systems have introduced Clinical Decision Support Systems (CDSS) platforms that are integrated with machine learning to assist with diagnostic decisions and to predict treatment outcomes. The CDSS analyses the EMR data fed by the clinicians, including test results from pathology laboratories, radiological departments, genetics departments and information stored in biobanks and databanks of genome sequences, and supplies diagnostic recommendations based on algorithms derived from rules informed by established clinical guidelines and published medical research reviews.[4] AI has been developed [5] in Singapore to aid in diagnosing symptoms caused by diabetic retinopathy [6] and to screen for glaucoma and age-related macular degeneration. It is also utilised to predict the risks of relapse for stroke patients through the use of computer vision and fluid dynamics to measure the speed of blood flow in arteries and veins. [7] During the COVID-19 pandemic, an AI tool called RadiLogic was used to detect abnormal chest X-rays for COVID screening in Singapore. [8] Experimental work on neural network classification based on medical datasets [9] has been carried out by researchers from Universiti Teknologi Malaysia.[10] Furthermore, machine learning models have been built using breast cancer data from

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[3] Anand Avati et al, 'Improving Palliative Care with Deep Learning' (2018) 18 (4) *BMC Medical Informatics and Decision Making*, https://doi.org/10.1186/s12911-018-0677-8.

[4] Tamra Lysaght, Hannah Yeefen Lim, Vicki Xafis and Kee Yuan Ngiam, 'AI-Assisted Decision Making in Healthcare: The Application of an Ethics Framework for Big Data in Health and Research' (2019) 11 (3) *Asian Bioethics Review* 299, doi.org/10.1007/s41649-019-00096-0.

[5] The AI was developed by the Singapore National Eye Centre (SNEC), the Singapore Eye Research Institute (SERI) and the National University of Singapore (NUS) School of Computing.

[6] See Channel News Asia, 'In a World First, Singapore-Developed Artificial Intelligence System Detects 3 Major Eye Conditions' (14 December 2017), www.channelnewsasia.com/news/health/in-a-world-first-singapore-developed-artificial-intelligence-9498742.

[7] See Nurfilzah Rohaidi, 'In Singapore's Healthcare Revolution, AI is the Key', www.govinsider.asia/inclusive-gov/singapores-healthcare-revolution-ai-key.

[8] The AI was trained on data consisting of 1,000 anonymised abnormal chest X-rays from COVID19 patients and 4,000 anonymised normal chest X-rays. See Shabana Begum, 'Coronavirus: AI Tool Developed to Detect Abnormal Chest X-rays Quickly' (3 September 2020), www.straitstimes.com/ singapore/ai-tool-developed-to-detect-abnormal-chest-x-rays-quickly.

[9] This includes datasets for the following conditions: Hepatitis, Heart Disease, Pima Indian Diabetes, Wisconsin Prognostic Breast Cancer, Parkinson's disease, Echocardiogram, Liver Disorders, Laryngeal 1 and Acute Inflammations.

[10] Zahra Beheshti, Siti Mariyam Hj Shamsuddin, Ebrahim Beheshti and Siti Sophiayati Yuhaniz, 'Enhancement of Artificial Neural Network Learning Using Centripetal Accelerated Particle Swarm Optimization for Medical Diseases Diagnosis' (2014) 18 *Soft Computing* 2253, https://doi.org/10.1007/s00500-013-1198-0.

the University of Malaya Medical Centre in order to identify the important prognostic factors for breast cancer survival.[11]

The use of AI has the potential to significantly reduce the time spent by medical doctors in diagnosis. It is able to scan a wide range of data to diagnose diseases more quickly and with lower error rates. As a starting point, it appears to be more economically efficient to use AI for medical services. Nonetheless, significant work is involved in supplying the AI with data so that it can provide sufficiently accurate diagnoses or predictive analysis. The quality of the AI analysis depends on the size of data used. In this regard, the availability of EMRs through the National Electronic Health Record in Singapore should play an increasingly important role.

Even as medical AI has progressed apace, the possibility of errors arising from its use cannot be underestimated. Consider these scenarios. The AI fails to diagnose a tumour and the patient's health condition deteriorates without timely treatment, or the AI prescribes the wrong drug or surgical procedure, causing adverse health effects to the patient. Moreover, errors from medical AI based on large datasets affecting patients admitted to a hospital may be more widespread than those committed by an individual human doctor. To what extent should medical doctors and hospitals using medical AI be legally responsible under existing tort laws in Singapore and Malaysia? What is the standard of care we expect from doctors and hospitals when using AI to provide medical services? To what extent should doctors and hospitals understand, evaluate and rely on black box medicine? Furthermore, where doctors and hospitals are found *not* to be at fault in the use of medical AI, should we nonetheless pin tortious responsibility on them for harms caused to patients? Th ere is currently no product liability legislation in Singapore and the product liability regime in Malaysia does not apply to medical services, but we will consider the applicability of the tort doctrines of vicarious liability and non-delegable duties to the use of medical AI.

This chapter only covers tort liabilities from the use of medical AI for the purpose of directly providing medical services to patients. Section II will focus on the common law tort rules on standard of care in Singapore and Malaysia, and how they may be *applied* or *adapted* for determining liability arising from the use of medical AI. The general standard of care and its two major legal tests will be discussed, followed by their applicability to specific issues: (i) the doctors' or hospitals' reliance on medical AI, designers and approving authorities; (ii) their omission to utilise medical AI; (iii) the impact of inaccuracies, bias and opacity of medical AI on standard of care; and (iv) the giving of medical advice based on AI output. In addition to the usual techniques of judicial reasoning such as the extension of existing legal rules by the use of analogical reasoning and incrementalism, the discussion will be framed by more general competing policy considerations impinging on tort liability such as efficiency, the promotion of technological innovations, the relevance of ethical guidelines applicable to the medical profession and patient welfare. Section III focuses on the question of whether the doctors and hospitals should be liable for errors arising from medical AI in

[11] Mogana Darshini Ganggayah, Nur Aishah Taib , Yip Cheng Har, Pietro Lio and Sarinder K aur Dhillon, 'Predicting Factors for Survival of Breast Cancer Patients Using Machine Learning Techniques' (2019) 19 *BMC Medical Informatics and Decision Making* 48, https://doi.org/10.1186/ s12911-019-0801-4.

the absence of fault on the basis of vicarious liability and non-delegable duties respectively. Section IV concludes.

II. Extending the Law of Medical Negligence in Singapore and Malaysia to Medical AI

Singapore's healthcare system has modernised at a rapid pace since independence. Its public sector comprising government-restructured hospitals and a number of large private hospitals provide secondary and tertiary hospital facilities offering specialist care and advanced medical diagnosis and treatment. Singapore serves as a hub for manufacturing operations of global pharmaceutical and medical technology companies partaking in biomedical research and development. With its modern healthcare system and facilities, Singapore undertook initiatives to boost medical tourism and foreign patient figures[12] two decades ago. However, in view of the public sector mission to ensure affordable healthcare, medical tourism is no longer promoted.[13]

Like Singapore, Malaysia delivers a mixed healthcare system from both the public and private sectors. There has been a noticeable shift from the government welfarist approach in healthcare to the commercialisation and corporatisation of medical services, and the growth of private hospitals and specialised clinics since the 1980s.[14] In Malaysia, private clinics and doctors outnumber those in the public sector and with a higher concentration in urban compared to rural areas. [15] Overall, in Malaysia, the scope of medical services has been comprehensive and delivered at a relatively low cost,[16] although it continues to face the challenge of increasing the number of medical staff in the public sector to deal with the patient load.[17]

Notwithstanding the growing evidence that AI can outperform human doctors in diagnoses,[18] it is not immune from errors. One important issue is how we should deal with injuries suffered by patients due to medical AI. Aside from the tort system, one alternative is to set up a no-fault system in which patients may obtain payments for medical injuries sustained without having to prove the fault on the part of the doctor or

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[12] Th e Healthcare Services Working Group working jointly with the Singapore Tourism Board, the Economic Development Board and International Enterprise Singapore.

[13] Jeremy Lim, *Myth or Magic: Th e Singapore Healthcare System* (Select Publishing, 2013) 145.

[14] Chee Heng Leng and Simon Barraclough, 'The Transformation of Health Care in Malaysia' in *Health Care in Malaysia: Th e Dynamics of Provision, Financing and Access* (Routledge, 2007) 1.

[15] Huy Ming Lim, Sheamini Sivasampu, Ee Ming Khoo and Kamaliah Mohamad Noh, 'Chasm in Primary Care Provision in a Universal Healthcare System: Findings from a Nationally Representative Survey of Health Facilities in Malaysia' (2017) 12 (2) *PLOS ONE*, https://doi.org/10.1371/journal. pone.0172229. The survey on primary care clinics was conducted from June 2011 to February 2012.

[16] See Safurah Jaafar et al, 'Malaysia Health System Review' (2013) 3 (1) *Health Systems in Transition*, ww.searo.who.int/entity/asia_pacific_observatory/publications/hits/hit_malaysia/en; see also Jenny Goh, 'Malaysia to Face a Nursing Shortage by 2020' *MIMS Today* (6 January 2017), www.today.mims.com/malaysia-to-face-a-nursing-shortage-by-2020 (on the shortage of nurses).

[17] 'Public of Private Hospitals? The Choice is Yours' Borneo Post Online (18 February 2011), www. theborneopost.com/2011/02/18/public-or-private-hospitals-the-choice-is-yours.

[18] A Michael Froomkin, Ian Kerr and Joelle Pineau, 'When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning' (2019) 61 (33) *Arizona Law Review* 33.

hospital. Such a system enjoys the advantages of simplicity and low transaction costs for the parties involved. In contrast, Malaysian commentators have recognised the practical problems in the implementation of the tort system evidenced by potential inefficiencies, costs and delays in the litigation system.[19] This may be exacerbated by the costs of medical expert witnesses, the confrontational courtroom setting for disputing parties and the spectre of defensive medicine practised by doctors who are concerned with potential lawsuits.[20]

However, unlike the no-fault-system, the tort system can play an important role in allowing for the full extent of compensation of losses, setting fault-based standards for the medical profession [21] and ensuring its accountability. Disputing parties need not undergo a full-blown litigation, but may choose mediation to settle medical negligence disputes. The adversarial nature of litigation can be tempered by a shift to an inquisitorial approach to settling disputes.[22] Pre-action protocols for medical negligence cases in Singapore[23] have been instituted with a view to obtaining resolution of disputes without protracted litigation. In practice, medical doctors, who are covered by compulsory indemnity, do not have to pay compensation directly to patients. The availability of such indemnity does not mean that doctors are not deterred by medical negligence claims. Legal actions can affect the amount of insurance premiums payable and the doctors' reputations, not to mention the time and costs in defending the claims.

Notwithstanding the above pros and cons concerning the most appropriate system to deal with medical injuries, the tort system on medical negligence is firmly established in both Singapore and Malaysia. For this reason, its full potential and possible role in the regulation of the use of medical AI must be investigated, even as we explore alternative or supplementary regulatory tools.

The issue of breach – a core aspect of medical negligence – is based on a number of factors: the foreseeability and probability of harm, the extent of harm, the costs of precautions to be undertaken, industrial practices and norms. This is to be balanced against the actual and potential benefits to be obtained from the innovation, such as the superior performance and speed of AI, as highlighted above. Though pegged to an objective standard of reasonableness, the standard of care when applied to technological innovations can fluctuate in tandem with the human expectations and understanding of and their evolving interactions with the technology.

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[19] Siti Naaishah Hambali and Solmaz Khodapanahandeh, 'Review of Medical Malpractice Issues in Malaysia under Tort Litigation System' (2014) 6 (4) *Global Journal Health Science* 76; Puteri Nemie bt Jahn Kassim, 'Medical Negligence Litigation in Malaysia: Whither Should We Travel?' (2004) 33 (1) *Journal of the Malaysian Bar* 14, 18.

[20] Paula Case, 'The Jaded Cliche of "Defensive Medical Practice": From Magically Convincing to Empirically (Un)Convincing?' (2020) 36 (2) *Professional Negligence* 49.

[21] Puteri Nemie bt Jahn Kassim, 'Medical Negligence Litigation in Malaysia: Whither Should We Travel?' (2004) 33 (1) *Journal of the Malaysian Bar* 14, 18

[22] Sundaresh Menon, Chief Justice of the Supreme Court of Singapore, 'Evolving Paradigms for Medical Litigation in Singapore', speech to the Obstetrical and Gynaecological Society of Singapore (2014).

[23] Supreme Court Practice Directions, Appendix J (High Court Protocol for Medical Negligence Cases), which took effect from 2017; and State Courts Practice Directions 39 (Medical Negligence Claims), which took effect from 1 October 2018.

The standard of care of a medical doctor is assessed based on his or her prevailing knowledge at the material time of the breach without the benefit of hindsight.[24] Hence, the doctor's standard should be judged by what he or she knows concerning the AI being utilised for medical services. If the AI was known to be functioning with great accuracy at the time of the breach, the doctor cannot be faulted for using the AI should it be discovered subsequently that the algorithm was insufficiently sophisticated to detect the patient condition and thereby resulted in a wrong diagnosis. Furthermore, we should not take account of subsequent media reports of mishaps or accidents relating to the use of medical AI or new scientific discoveries regarding the flaws, inaccuracies or weaknesses of the AI in order to show that the doctor was negligent.

Our main focus is on AI errors impinging on medical diagnosis, treatment and advice that result in a patient's injuries. This chapter adopts a judicial approach to resolving a medical negligence dispute focusing on legal principles, doctrines and policy considerations when applied to novel technology. We will first look at the legal standard of care expected of medical doctors when dealing with medical innovations such as AI before discussing specific scenarios and challenges posed by AI.

A. *Bolam*, *Bolitho* and the Standard of Care in the Use of Medical AI

In the event of conflicting expert evidence on the standard of care expected of medical doctors, two legal tests are applied to determine whether there has been any negligence in medical diagnosis and treatment. The *Bolam* test[25] – in stating that a doctor is not negligent if he or she has acted in accordance with a practice accepted by a responsible body of medical doctors – is deferential to the medical profession's views. In *Hunter v Hanley* , Lord President Clyde stated that '[i]n the realm of diagnosis and treatment, there is ample scope for genuine difference of opinion'.[26] When new AI is being developed for use in diagnosis and treatment, such differences in opinion on the scope of the use of medical AI and the doctor ' s negligence may arise. Th us, a mere mistake in diagnosis or treatment does not necessarily amount to negligence on the part of medical doctors. As the *Bolam* test considers the doctor's act or omission viewed by the medical profession at the time of the alleged breach, a finding of negligence 'reasoned through hindsight, hindsight bias and outcome bias from the plaintiff's adverse outcome' may be avoided.[27]

If the *Bolam* test is satisfied, the courts proceed to a second inquiry – the addendum in *Bolitho v City and Hackney Health Authority* [28] – which requires that the medical opinion be subject to the requirement of logic and the weighing up of comparative risks and benefits to reach a defensible conclusion. Hence, when there is 'genuine medical

[24] *Roe v Minister of Health* [1954] 2 QB 66.
[25] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587.
[26] Hunter v Hanley [1955] SLT 213, 217.
[27] Jem Barton-Hanson and Renu Barton-Hanson, '*Bolam* with the Benefit of Hindsight' (2016) 56 (4) *Medicine, Science and the Law* 275.
[28] *Bolitho v City and Hackney Health Authority* [1998] AC 232.

controversy', the courts should not prefer one medical opinion over another unless the medical opinion is illogical.[29] Essentially, in applying *Bolitho*, the court rather than the medical profession will decide on the standard of care required of the defendant. The Singapore Court of Appeal in *Khoo James v Gunapathy d/o Muniandy* [30] laid out a two-stage analysis based on the *Bolitho* addendum: (a) whether the expert had directed his or her mind to the comparative risks and benefits; and (b) whether the expert had arrived at a ' defensible' conclusion in relation to two factors: (i) whether the medical opinion was internally consistent on its face, and (ii) whether the opinion ignores or is contrary to known medical facts or advances in medical knowledge.

Let us assume that the patient claims that the doctor was negligent in using AI to diagnose the patient's condition. Given the requirement of an existing 'practice' of a responsible body of medical opinion, it would be difficult (though not impossible) to apply the *Bolam* test to a situation where the AI technology in question is at the cutting edge. In this sense, *Bolam* is generally inappropriate for assessing the use of AI innovations which have yet to be adopted (much less accepted as proper) by at least a respectable body of medical opinion. At the same time, this responsible body of opinion is not to be treated as merely a quantitative matter. A small but responsible body of medical opinion can qualify under the *Bolam* test.[31]

Even if *Bolam* is applicable, the *Bolitho* test demands an explanation by the defendant experts as to the logical basis for their opinion that the use of medical AI was acceptable. The opacity of medical AI may make it difficult for the experts to justify their opinions in considering the comparative benefits and potential risks from the use of medical AI. This will be further discussed below.[32]

In addition, the *Bolitho* test demands internal consistency within the expert opinion and external coherence of the expert opinion with the state of existing medical knowledge. At present, it is not clear whether the state of and advances in medical knowledge would include knowledge of medical AI, as the latter is not normally regarded as within the domain expertise of doctors. But we should not discount the possibility that the use of medical AI would in the near future become so prevalent amongst doctors such that they would be expected to possess knowledge of certain types of medical AI as part of clinical practice.[33] Information of such medical AI may in future be commonly found in medical journals and literature which doctors may need to keep abreast of.

Though there may be difficulties in applying the *Bolam* and *Bolitho* tests directly to medical AI, the tort of medical negligence can nevertheless accommodate AI

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[29] *Noor Azlin bte Abdul Rahman v Changi General Hospital Pte Ltd and Others* [2019] 1 SLR 834 [65].

[30] *Khoo James v Gunapath* y *d/o Muniandy* [2002] 1 SLR(R) 1024 (hereinafter *Gunapathy*).

[31] *De Freitas v O'Brien and Connolly* [1995] 6 Med LR 108. The court held that 11 doctors specialising in spinal surgery out of more than 1,000 orthopaedic and neurosurgeons in the country constituted a responsible body of opinion.

[32] See section II.D below.

[33] For example, at Yong Loo Lin School of Medicine at the National University of Singapore, medical students attended workshops on Health Informatics, and other workshops on AI and machine learning were being planned; see Dr Kenneth Ban, 'Health Informatics – Equipping Students with Skills for the Digital Age' (November 2019), www.medicine.nus.edu.sg/newsletters/issue-32/insights/health-informatics-equipping-students-with-skills-for-the-digital-age.

innovations. First, the mere fact that the doctor's use of medical AI deviates from existing medical practice does not in itself amount to negligence. Otherwise, it would not be feasible at all to introduce any medical innovations in clinical practice. Such a proposition was endorsed in *Rathanamalah d/o Shunmugam v Chia Kok Hoong*,[34] in which a novel surgical technique, or novel combination of surgical procedures,[35] was used by the doctor. The expert evidence indicated that the novel technique gave rise to a potential benefit, posed minimal risk and even had the potential to reduce the risk of injury. Furthermore, there was no evidence that no responsible body of medical opinion, logically held, would support such innovation,[36] and the doctor was found not to be negligent in using the innovative technique.

Gobinathan Devathasan v SMC [37] is a medical disciplinary case on the novel use of therapeutic ultrasound on a patient who was suffering from a neurological syndrome. Although *Gobinathan* is not a claim in negligence, its general thrust is aligned with *Rathanamalah*. The Singapore High Court held that where a medical doctor embarks on a novel treatment that is not generally accepted by the profession but which the doctor thinks is beneficial to the patient, the latter will have to show that the novel treatment poses no harm to the specific patient. Th is, according to the court, seeks to strike a balance between promoting innovation and progress and the particular patient's well-being.[38] There is no requirement for the medical doctor to additionally prove that the novel treatment is beneficial to patients generally.

The above cases show that safety, the minimisation of harm and benefits are key, a position in line with section B6 (Untested Practices) of the SMC Ethical Code and Ethical Guidelines (ECEG 2016) that endorse the minimisation of harm principle: 'Patients expect doctors to off er only treatments or therapies that will benefit them while minimising harm.' The ECEG 2016 also states that doctors must treat patients only according to 'generally accepted methods, based on a balance of available evidence and accepted best practices'. This guideline extends to new medical devices. According to *Pang Ah San v SMC*, [39] a particular treatment is generally accepted where 'the potential benefits and risks of that treatment and the ability to control these are approaching a level of predictability that is acceptable to the medical community in general'. There are other situations where innovations may be utilised. Innovative therapy may be offered when conventional therapy is 'unhelpful and it is a desperate or dire situation'. Moreover, 'experimental and innovative treatment which is *therapy* administered in the best interests of the patient is permissible'.[40]

Thus, from the macro-policy perspective, medical innovation plays an important role in *ex ante* regulation whether through disciplinary actions or medical negligence

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[34] *Rathanamalah d/o Shunmugam v Chia Kok Hoong* [2018] 4 SLR 159 [127] (Aedit Abdullah JC). *cf Hepworth v Kerr* [1 995] 6 Med LR 139, where the defendant anaesthetist was negligent in experimenting with new hypotensive anaesthetic technique which exposed the patient to excessive risk.

[35] Foam sclerotherapy was used in combination with endovenous laser therapy to treat a patient diagnosed with venous eczema.

[36] *Rathanamalah* (n 34) [127].

[37] *Gobinathan Devathasan v SMC* [2010] 2 SLR 926.

[38] ibid [62].

[39] *Pang Ah San v SMC* [2014] 1 SLR 1094 [55], [56].

[40] ibid [61].

claims. The Singapore High Court in *Pang Ah San* couched the issue in the disciplinary action as follows: ' How does the current regulatory regime balance the need to ensure the safety of patients without stifling innovation which might benefit patients?'[41] Such a sentiment was echoed by the Singapore Court of Appeal in *Hii Chii Kok v Ooi Peng Jin London Lucien*.[42] It had considered imposing a stricter standard as an alternative to the *Bolam* and *Bolitho* tests for assessing the standard of care of medical doctors in diagnosis and treatment, but rejected the idea due to the potential adverse impact on innovations:

> [R]eplacing the *Bolam* test and *Bolitho* addendum with a more demanding standard may encourage therapeutic and scientifi c conservatism, as doctors might be incentivised to cling to the most established and mainstream approaches regardless of their relative effectiveness. Such an undue focus on orthodoxy could well discourage innovation and unnecessarily prolong the lifespan of 'best practices' which, in truth, may be inferior to newer but less established competing practices.[43]

S econd, the argument for applying the *Bolam* test to assess standard of care in diagnosis and treatment – that medical doctors with their medical expertise are better positioned to decide on the intricacies of diagnosis and treatment where genuine differences of opinion exist – is less persuasive when assessing the use of medical AI. This is because medical doctors, as it stands, do not necessarily have the requisite expertise in medical AI. In fact, they would likely require some training from software developers and designers or AI providers prior to the deployment of novel medical AI for their clinical practice. Again, as mentioned above, such a position can change over time as the use of medical AI becomes more prevalent.

Finally, we must remember that the *Bolam* and *Bolitho* tests do not constitute the whole of the reasonable doctor standard. The Singapore Court of Appeal in *Hii Chii Kok* had observed that the *Bolam* and *Bolitho* tests are merely heuristics to aid the courts in determining the standard of care of doctors. What is ultimately crucial is whether the doctor acted reasonably. [44] Applying this principle to medical AI, the main inquiry should be whether it would be reasonable for the doctor to use medical AI given a holistic assessment of the risks and benefits of the innovation without being confined exclusively to the medical expert opinions.

With respect to technological innovations generally, Henderson [45] argues that the negligence rule allows for the balancing of risks of technological innovations and likelihood with the costs of precaution. As mentioned above, the non-hindsight rule ensures that doctors would not be responsible for the effects of technological innovations which were not apparent at the time of the alleged breach of duty. The dangers of hindsight bias – that the new or increased knowledge and experience from the use of medical AI after the event should not be utilised to render the doctor liable

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[41] ibid [2].
[42] *Hii Chii Kok v Ooi Peng Jin London Lucien* [2017] 2 SLR 492 (CA).
[43] ibid [82].
[44] ibid [104].
[45] James A Henderson Jr, 'Tort vs Technology: Accommodating Disruptive Innovation' (2015) 47 *Arizona State Law Journal* 1145.

for negligence – were specifically highlighted by the Singapore Court of Appeal in *Hii Chii Kok*.[46]

Admittedly, the negligence standard does not always give certainty in terms of judicial outcomes and is based on *ex post* regulation. Indeed, in view of the nature of the evolving technology and implementation of medical AI, some uncertainty is inevitable. Nonetheless, negligence principles and their application to medical AI can be refined over time based on the overarching objective standard that is capable of balancing competing considerations in a way that is sensitive to the contexts and the risks involved.

B. (Un)Reasonable Reliance on Medical AI and Related Parties

The medical doctor or hospital may seek to absolve themselves of liability on the basis that reasonable reliance was placed on the AI developers or the authority approving the use of AI. The use of medical AI in Singapore requires the approval of the Health Sciences Authority[47] under the category of 'medical devices' as stated in the Health Products Act.[48] For example, the developers of Selena+ (or Singapore Eye Lesion Analyser plus) – a deep learning system to analyse retinal photographs to detect diabetic eye diseases – had sought approval from the Health Sciences Authority (HSA).[49] The HSA has recently approved the use of an AI-powered software – Augmented Vascular Analysis (AVA) – as a class B device for the automated analysis and reporting of vascular ultrasound scans.[50]

Under the Health Products (Medical Devices) Regulations 2010, the two main criteria are the intended use of the medical device and the health risks posed to the end-user (i.e., the patient). The medical devices are classified according to the risks involved.[51] Registration of the medical device will be allowed where the 'overall intended benefits to an end-user of the medical device outweigh the overall risks' and it is 'suitable for its intended purpose and that any risk associated with its use is minimised'.[52] The intended purpose also has to conform to the safety and performance requirements for the medical device.

To deal specifically with AI-driven medical devices, the HSA issued in December 2019 the *Regulatory Guidelines for Software Medical Devices – A Lifecycle Approach*. One section of the *Regulatory Guidelines* pertains to pre-market registration for

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[46] *Hii Chii Kok* (n 42) [159], citing *Rosenberg v Percival* [2001] HCA 18 [68] and *Maloney v Commissioner for Railways* (1978) 18 ALR 147, 148. The court in *Rosenberg* noted that perfection or the use of increased knowledge or experience embraced in hindsight after the event should form no part of the components of what is reasonable in all the circumstances.

[47] The governing laws are the Health Products Act (Cap 122D, Rev Ed 2008) and the subsidiary legislation (Health Products (Medical Devices) Regulations 2010).

[48] Health Products Act (Cap 122D, Rev Ed 2008), sched 1.

[49] Timothy Goh, 'An AI for the Eye' *The Straits Times* (6 July 2019), https://www.straitstimes.com/singapore/health/an-ai-for-the-eye.

[50] Eileen Yu, 'Singapore Approves AI for Vascular Ultrasound Scans' (1 0 December 2019) , www.zdnet.com/article/singapore-approves-ai-for-vascular-ultrasound-scans.

[51] See the Third Schedule.

[52] Health Products (Medical Devices) Regulations 2010, cl 25.

Artificial Intelligence Medical Devices (AI-MD) as well as process controls and validations to monitor the learning and evolving performances of devices with continuous learning capabilities. Product registration entails the provision of various categories of information relating to the input data and features (such as the patient's historical records, diagnostic images and medication records), the training, validation and test datasets, the AI model selection, the device workflow (e.g., whether it is human-in-the-loop) and so on.[53]

Assuming the medical AI is approved for use by the authorities, can the medical doctor or hospital justify their reliance on the AI developers and/or approving authorities? According to the Singapore case of *TV Media Pte Ltd v De Cruz Andrea Heidi*,[54] the defendant, an importer and distributor of slimming pills, could not absolve negligence liability by placing 'unquestioning reliance' on a health-approving authority with respect to certain pills that caused the plaintiff's injuries. In that case, there were suspicious circumstances arising from tests conducted on the pills. If this argument were to be used in the context of medical AI, the doctor would have to show that he or she had reasonably relied on the AI developers and/or approving authorities as opposed to placing mere unquestioning reliance. If the doctor were aware that certain aspects of the medical AI (such as the training data or its method of implementation) might enhance the risks of errors or bias, such reliance on the AI developers and/or approving authority would not be reasonable.

To determine the reasonableness or otherwise of reliance on medical AI which has been approved as a medical device, we should consider the authority's scope of approval, the review process before granting approvals and the knowledge of the medical doctor regarding such processes. The extent of the medical doctor's reasonable reliance on AI should also depend on whether the AI is employed either as a primary diagnostic or treatment tool or is merely used as an ancillary diagnostic or treatment tool to provide statistics or analysis to assist and/or complement the doctor in the treatment of the patient.

Useful analogies may also be drawn from existing law relating to the medical doctor's reliance on non-AI medical diagnostic or predictive tools. In the Singapore High Court decision of *Hii Chii Kok v Ooi Peng Jin London Lucien*,[55] the doctor's heavy reliance on the high positive predictive value of the patient's Gallium scan for a specific type of tumour was justified on the grounds that the Gallium scan was the most 'sensitive and advanced diagnostic tool' available for the detection of the tumour, the results of malignancy being based on 'the state of learning at that time' and that the 'index of suspicion' was raised due to the hotspots indicated by the patient's Gallium scan.[56] Th ese grounds relating to the sensitivity and sophistication of the tool and the level of suspicion from observed symptoms based on medical knowledge at the relevant time are arguably valid considerations for assessing the reasonable use of medical AI.

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[53] See the US Food and Drug Administration (FDA)'s White Paper, 'Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)', www.fda.gov/media/122535/download .

[54] *TV Media Pte Ltd v De Cruz Andrea Heidi* [2004] 3 SLR(R) 543 [71].

[55] *Hii Chii Kok v Ooi Peng Jin London Lucien* [2016] 2 SLR 544 (Chan Seng Onn J).

[56] ibid [162].

C. (Un)Reasonable Omission to Utilise Medical AI

Would the medical doctor be liable to a patient who suffers injury as a result of the doctor's omission to use AI? AI may be able to detect patterns in the training data for the purpose of diagnosis which doctors are unable to find. Topol[57] refers to System 1 thinking for medical diagnosis, which is automatic, quick and intuitive using heuristics (or rules of thumb) rather than System 2 deliberative thinking, and that System 1 thinking is prone to cognitive biases in doctors. Moreover, doctors do not deal with as wide a range of patient data as an AI system with a large dataset. For example, it was reported that IBM Watson diagnosed a rare form of leukaemia which was overlooked by the University of Tokyo treatment team.[58] Where AI is known to deliver more accurate diagnosis or treatment compared to human doctors, but the doctor refuses to use medical AI that was made available to him or her without any cost impediments, he or she is likely to be prima facie in breach for his or her own error in diagnosis which resulted in the patient's injury unless justified on other grounds (e.g., lack of general practice for its use).

We can draw analogies from cases on the omission to use technology. The US court in *The TJ Hooper* [59] held that it was negligent for a tugboat not to have a working radio on board to receive up-to-date storm weather warnings. Most tugboats did not have any at that time, though the technology was readily available, relatively inexpensive and, if used consistently, would potentially prevent the accident in question. Justice Learned Hand in *The TJ Hooper* stated:

> In most cases reasonable prudence is in fact common prudence; but strictly speaking it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not exclude their omission.[60]

Indeed, it is the court that will ultimately decide on reasonableness and legal liability. Nonetheless, the liability for the omission to use technology depends to a large extent on the existence of a general practice relating to its use. In *BNM v National University of Singapore*, [61] the university was found not to be liable for failing to provide automated external defibrillators at its swimming pool as the significance of having defibrillators at the pools had ' not yet coalesced into a general practice', even though there was 'an emerging acceptance' at that time.[62] Reference was also made to authoritative bodies which might be able to provide guidance on the prevailing

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[57] Eric Topol, *Deep Medicine* (Basic Books, 2019) 43.

[58] Bernie Monegain, 'IBM Watson Pinpoints Rare Form of Leukemia after Doctors Misdiagnosed Patient' *Healthcare IT News* (8 August 2016), www.healthcareitnews.com/news/ibm-watson-pinpointsrare-form-leukemia-after-doctors-misdiagnosed-patient.

[59] *The TJ Hooper*, 60 F 2d 737 (2d Cir 1932).

[60] ibid 740.

[61] *BNM v National University of Singapore* [2014] 4 SLR 931 [54].

[62] *cf Thompson v Smiths Shipbuilders (North Shields) Ltd* [1984] QB 405. In this case, the court held that it was the defendant's responsibility to provide protective equipment when social awareness arose as to the dangers of deafness due to industrial noise.

standards.[63] Extrapolating from this principle, the omission to use medical AI may be unreasonable only when there is a general practice regarding its use. That said, such general practices and standards, though an important factor, are not determinative as they may be regarded as too lax. The overarching standard of reasonable care would still govern.

Another possible allegation might be that the doctor failed to discharge his or her duty of keeping abreast of medical developments and technology. Again, this duty is not absolute, but is based on reasonable care. The fact that a medical doctor was not aware of certain medical information in medical journals that was relevant for the diagnosis or treatment of a patient did not necessarily mean that he or she was negligent.[64] However, it is a different situation when an AI-driven knowledge interface such as Watson is made available to the doctor, and the doctor fails to consider the AI results derived from the AI's review of millions of patterns of a disease. It would call for an explanation from the doctor should the patient be diagnosed wrongly. Existing case law supports the position that a doctor may be adjudged negligent in failing to use assistive diagnostic tools to help him or her make more accurate diagnoses.[65] Considerations of relative costs and utility of the medical AI would also be relevant here. As diagnostic AIs improve over time and become more affordable and commonly used, there would likely be increased 'legal' pressure on doctors and hospitals to make use of them in medical diagnosis.[66]

A more controversial situation may arise where the doctor uses medical AI diagnostics, but decides to override the decision made by the AI. Where the medical AI is known or generally accepted to be reliable, and the practice of using that medical AI for the provision of specified medical services has been generally accepted as proper, it is argued that the defendant doctor would have to provide concrete justifications for his or her decision (such as the potential risks of inaccuracy or bias) if and when he or she wishes to override the decisions from the medical AI output.

D. Inaccuracy, Bias, the Opacity of Medical AI and the Standard of Care

The problem of potential bias and inaccuracies from AI are well documented. This can sometimes occur when the AI operates from logical processes based on the inputs fed into the system without the benefit of human intuition and common sense. Machine learning has, for instance, wrongly predicted that patients with both pneumonia and asthma are in better condition than those with pneumonia only and that such patients should be discharged, even though they are in fact of higher risk. The wrong predictions arose because the patients with a history of asthma were directly taken to the intensive

[63] *BNM* (n 61) [54].
[64] *Crawford v Charing Cross Hospital*, *The Times*, 8 December 1953; *Dwan v Farquhar* [1988] 1 Qd R 234.
[65] *Bergen v Sturgeon General Hospital* (1984) 38 CCLT 155; *Smith v Salford HA* [1994] 5 Med LR 321.
[66] Froomkin, Kerr and Pineau (n 18).

care unit, which meant their files rarely appeared in the 'requires further care' data category; as a result, the algorithm classified them as low risk.[67]

Bias or errors can also arise from flawed or badly designed algorithms, or where the training data fed into the AI system may not be sufficiently comprehensive or representative of the population. For example, where there is a significantly disproportionate number of images of lesions on dark skins made available in the training data, the output may manifest biases against darker-skinned individuals. Moreover, there could be a mismatch between the training and operational data which requires adaptation to new patient contexts.[68] Despite the greater efficiency and speed of AI generally in medical diagnosis, AI may in fact perform worse than human doctors in these specific scenarios.

It is argued that legal liability under the tort of negligence should depend on the doctors' and hospitals' level of control over the training data or algorithms, their extent of knowledge of possible inaccuracies or biases, their ability or otherwise to take steps to modify or remove the data or bias, and the extent to which the AI can explain the outputs or process.

It should be noted that not all harms from biased medical AI are relevant in pinning legal liability on doctors and hospitals. For example, biased training data may generate outputs that wrongly predict health conditions of certain disadvantaged groups and, as a result, doctors do not provide the proper treatment for members of those disadvantaged groups. But it is not always easy to prove that the patient in question is a member of the disadvantaged classes who had in fact suffered the damage arising from the doctor's negligence in relying on medical AI.

In litigation proceedings, the doctors may be put on the stand to explain his or her decision for the diagnosis or treatment in connection with the AI output. Currently, the machines learn based on the recognition of patterns from the training data. They are adept at finding correlations. However, learning machines may not have the capability to provide *causal* explanations to questions such as 'What if I had acted/omitted?' or the retrospective 'What if I had acted differently?' based on counterfactual analysis. That causal reasoning in machines may form part of the drive towards strong AI[69] is a matter of consideration for the future. If the AI cannot explain its decisions in human-interpretable terms, what can be reasonably expected of the doctor in terms of giving an explanation?

Price[70] suggests that even though healthcare providers would find it difficult to evaluate the substantive accuracy and reliability of opaque medical AI, they should nonetheless exercise due care to evaluate the procedural quality of the AI (e.g., by examining the expertise of the developer and performing independent external validation). Hence, based on Price's proposal, the subject matter of the standard of care

[67] Kate Crawford and Ryan Calo, 'There is a Blind Spot in AI Research' (2016) 5 38 *Nature* 3 11, www.nature.com/news/there-is-a-blind-spot-in-ai-research-1.20805.
[68] Robert Challen et al, 'Artificial Intelligence, Bias and Clinical Safety' (2019) 28 *BMJ Quality Safety* 2 31.
[69] Judea Pearl, 'Theoretical Impediments to Machine Learning with Seven Sparks from the Causal Revolution' (January 2018), www.arxiv.org/pdf/1801.04016.pdf.
[70] W Nicholson Price, 'Medical Malpractice and Black-Box Medicine' in Glenn Cohen, Holly Lynch, Effy Vaynea and Urs Gasser (eds), *Big Data, Health Law, and Bioethics* (Cambridge University Press, 2018).

shifts from exercising care in respect of the patient's diagnosis and treatment to exercising care in scrutinising AI quality. With regard to the use of algorithms in AI models generally, other procedural measures include the reproducibility of results using the same AI model, the traceability of the AI's decisions and the datasets, and the auditability of algorithms by internal or external assessors.[71] The need for procedural validation may depend on the assessment of risks by the clinics and hospitals involved in the use of medical AI as part of their quality assurance obligations. This also relates to the point highlighted above on assessing the hospital's or doctor's reasonable reliance on the approving authorities and developers when assessing their standard of care in the use of medical AI for patient care.

In addition, the explainability of AI does not exist in a vacuum, but should be balanced against other values (such as the accuracy of outputs, the consistency of performance, and the nature and extent of the risks involved) when assessing the standard of care of doctors and hospitals.[72] Where the AI system is known to produce accurate results (e.g., 99 per cent accuracy in diagnosing particular illnesses) and consistency in observable effects for sustained periods, but the outcomes cannot be explained, should doctors and hospitals use such medical AI? Aft er all, not all medical outcomes are supported by underlying theoretical or causal explanations. For example, the scientific explanation as to why electroconvulsive therapy can treat severe depression and other mental disorders remains elusive, though it is widely used with the informed consent of patients.[73] In the medical domain, the pathophysiological disease is often uncertain and clinical practice is largely based on accumulated experience, empirical and clinical findings as opposed to explanations underlying a universal causal system.[74]

It is thus suggested that medical AI without such causal explanations may be used with the patient's informed consent,[75] subject to certain caveats. First, its accuracy rate for diagnosis should be superior to that of human doctors. Second, we would need to enquire if its accuracy can be verified by reference to independent evidence (such as the positive responses of the patients to treatment based on the AI diagnosis). If so, such AI diagnosis should be relied upon in the short term if there are significant health benefits for patients and provided the risks of relying on the AI are not grave. The explainability of the AI should remain a medium- to long-term target, but may arguably be sacrificed

[71] Personal Data Protection Commission, 'A Proposed Model Artificial Intelligence Governance Framework' (January 2020), www.pdpc.gov.sg/-/media/files/pdpc/pdf-files/resource-for-organisation/ai/sgmodelaigovframework2.pdf, paras 3.25 ff.

[72] Phillip Hacker , Ralf Krestel , Stefan Grundmann and Felix Naumann, 'Explainable AI under Contract and Tort Law: Legal Incentives and Technical Challenges' (2020) *Artificial Intelligence and Law*, www.doi.org/10.1007/s10506-020-09260-6.

[73] Neuroimaging studies have revealed anticonvulsant effects (decreased blood flow and decreased metabolism) in the frontal lobes, and neurotrophic effects (increased perfusion and metabolism and increased volume of the hippocampus) in the medial temporal lobes: see Christopher C. Abbott et al, 'A Review of Longitudinal Electroconvulsive Therapy: Neuroimaging Investigations' (2015) 27 (1) *Journal of Geriatric Psychiatry and* Neurology 33 doi.org/10.1177/0891988713516542.

[74] Alex John London, 'Artificial Intelligence and Black-Box Medical Decisions: Accuracy versus Explainability' (2019) 49 (1) *Hastings Centre Report* 15, 17, doi.org/10.1002/hast.973.

[75] See section II.E below.

in the short term, provided there is clear independent evidence of the superiority of AI diagnosis and its accuracy.

E. Medical Advice Based on AI Output

The giving of medical advice directly by medical AI without human doctors in the loop may become a reality in the future. The task requires the AI to understand patients' subjective preferences and values, which may be challenging for medical AI at this current stage of development. At present, the more plausible scenario is one where the human doctor gives medical advice to the patient based on the medical AI outputs that the doctor has had an opportunity to review. Should doctors disclose to the patient the roles and risks of emerging technology such as medical AI in the giving of medical advice? Should they reveal information concerning the risks of inaccuracy and bias in the medical AI used for diagnosis, prediction of risks or treatment? For instance, AI-assisted CDSS can predict, in real time, the patient's chance of survival to discharge and their ability to recover.[76] If there is a significant risk that the AI predictive analysis might be inaccurate due to the lack of representative training data at the relevant time, should such risks be disclosed to the patient when giving medical advice?

In Singapore, the Parliament has recently passed amendments to the Civil Law Act[77] concerning the standard of care expected of medical practitioners when giving medical advice. In essence, the new section 37 stipulates that the standard of care for medical advice is based on 'peer professional opinion' in line with the *Bolam* (deference to a respectable body of medical opinion) and *Bolitho* (logic) tests.[78] Such peer professional opinion must require the medical practitioner to give to the patient: (i) information which the patient would reasonably require to make an 'informed decision about whether to undergo treatment or follow a medical advice'; and (ii) information that the medical practitioner 'knows or ought reasonably to know is material to the patient' for the purpose of making such informed decision.[79] The materiality of information would be assessed based on any specific queries or concerns raised by the patient to the treatment or medical advice which has been *either* expressly communicated by the patient to the medical doctor *or*, in the absence of express communications, which would be apparent to the medical doctor from the patient's medical records to which the doctor has reasonable access and ought reasonably to review.[80] Furthermore, the peer professional opinion must support the non-provision of the abovementioned information to the patient only where there is reasonable justification (for example, in cases of an emergency life-saving situation and where the patient waives his or her right to the information).[81] The reasonable patient perspective and the justifications for the non-provision of information are similar to those enunciated in the Court of Appeal

[76] Lysaght et al (n 4) 309.
[77] Civil Law (Amendment) Bill No 33/2020. At the time of writing, the law has yet to take effect.
[78] Civil Law Act, s 37(1).
[79] ibid s 37(2)(a).
[80] ibid s 37(3).
[81] ibid s 37(2)(b) and the illustrations.

decision in *Hii Chii Kok*, [82] which had in turn adapted the UK Supreme Court's approach in *Montgomery v Lanarkshire Health Board*. [83] Hence, insofar as medical advice is concerned, the *Hii Chii Kok* approach has been substantially integrated within the general framework of the *Bolam* and *Bolitho* tests.

With respect to information that the patient would consider relevant and material, the court in *Hii Chii Kok* had referred to factors such as the likelihood of the risk as well as the severity of the consequences.[84] Relevant information would include the benefits and likely side-effects or risks from a recommended treatment, and also the advantages and disadvantages of alternative procedures and of non-treatment[85] – and with respect to diagnosis, the degree of certainty of a diagnosis, the reasons for the lack of certainty and ' whether more could be done to clarify the uncertainty'.[86]

In comparison, the Malaysian common law position is encapsulated in *Foo Fio Na v Dr Soo Fook Mun*. [87] Insofar as medical advice is concerned, the Malaysian Federal Court favoured the Australian test in *Rogers v Whitaker* [88] that the courts should 'adjudicate on what is the appropriate standard of care after giving weight to the paramount consideration that a person is entitled to make his own decisions about his life'[89] instead of the *Bolam* test. It has in two subsequent cases[90] affirmed that the principle in *Foo Fio Na* applied only to medical advice and not diagnosis and treatment. Further, as observed by the Malaysian Federal Court in *Dr Hari Krishnan v Megat Noor Ishak bin Megat Ibrahim*, [91] the doctor's obligation to explain the risks to which a reasonable patient would attach significance extended beyond giving general precautions of risks of the operation in the consent form signed by the patient. For diagnosis and treatment, on the other hand, *Bolam* and *Bolitho* will continue to apply to determine the standard of care with respect to medical diagnosis and treatment.[92]

Applying this to medical AI, the first point to highlight is that just as doctors do not have to share with patients the equipment, methods, prior training and medical treatises they rely on in coming to a decision on diagnoses or treatment, there is no general obligation for doctors or hospitals to disclose the use of medical AI. There does not appear to be any violation of patient autonomy here. Prima facie, the equipment, methods, training and medical treatises per se relied upon by the doctor do not relate to the risks to which a reasonable patient would attach significance under Malaysian law.

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[82] *Hii Chii Kok* (n 42) [132].
[83] [2015] UKSC 11; [2015] 1 AC 1430.
[84] *Hii Chii Kok* (n 42) [140].
[85] ibid [142], [146].
[86] ibid [143].
[87] *Foo Fio Na v Dr Soo Fook Mun* [2007] 1 MLJ 593.
[88] *Rogers v Whitaker* [1992] 175 CLR 479.
[89] Cited in *Foo Fio Na* (n 87) [47].
[90] *Zulhasnimar bt Hasan Basri and Another v Dr KuppuVelumani P and Others* [2017] 5 MLJ 438; *Dr Hari Krishnan v Megat Noor Ishak bin Megat Ibrahim* [2018] 3 MLJ 281.
[91] *Dr Hari Krishnan* (n 90) [73], [74].
[92] But note the Malaysian Court of Appeal decision in *Ahmad Zubir bin Zahid (Suing by Himself and as the Administrator of the Estate of Fatimah bt Samat, Deceased) v Datuk Dr Zainal Abidin Abdul Hamid and Others* [2019] 5 MLJ 95, which continues to cite *Foo Fio Na* (which adopted the *Rogers v Whittaker* approach, but rejected *Montgomery* without explaining the differences, if any, between *Rogers* and *Montgomery*).

In Singapore, the obligation arises only with respect to information given by the medical doctor that, in the peer professional opinion, the patient would reasonably require in order to make an informed decision and information that is material to the patient about whether to undergo the treatment or follow the medical advice. Material information in this regard would likely include, as mentioned in *Hii Chii Kok*, uncertainties in the diagnosis, the risks and benefits of the treatment, complications and options.[93] Though these factors are not specifically provided for in the Singapore statutory amendments, they are consistent with the scope of the materiality of information pertaining to the patient's decision as to whether to undergo treatment or follow medical advice stated in section 37.

If the medical AI comes up with a diagnosis of the patient's skin lesions that are quite rare based on training data (images of such lesions), would the doctor have to disclose the inadequacies of the training data? Commenting on the use of a particular scan by the doctor for diagnosis in *Hii Chii Kok*, the patient alleged that the defendants had failed to inform him that the Gallium PET/CT scan 'was a newly introduced scan and had only been used in 20 patients and particularly only in 5 instances' to diagnose the disease. The Singapore Court of Appeal said that it was not necessary to disclose such specific information,[94] but that a reasonable patient would wish to know 'the limitations of the Gallium scan, and, in particular, that there was a possibility that the scan results could have identified false positives – not the specific number of times the scan had previously been used'. [95] Extrapolating to medical AI, the material limitations if any of the medical AI used for diagnosis and the potential unreliability of the outcomes generated (from inadequate training data) would arguably be relevant and material information for disclosure.

W here the proposed treatment via medical AI is experimental or novel, should the doctor be obliged to disclose such information? In *Gunapathy*, the technique of laser radiosurgery known as 'XKnife'[96] used by the defendant doctor was experimental at the relevant time.[97] The Singapore Court of Appeal, applying the *Bolam* and *Bolitho* tests to medical advice without the benefit of the 'material' risks test viewed from the patient's perspective, did not consider the omission to disclose the experimental nature of the technique to be relevant for assessing the neurosurgeon's standard of care.[98] Based on the current statutory position in Singapore and *Foo Fio Na* in Malaysia for medical advice, it could be argued that the experimental nature of the technique would be 'material' to the patient where it is linked to the risks of laser radiosurgery to treat a

[93] *Hii Chii Kok* (n 42) [138] – [146].

[94] *cf Johnson v Kokemoor* 5 45 NW 2d 495, 498 (Wis 1996), where the court held that information concerning a physician's relative inexperience in performing a particular procedure and his risk statistics compared to other physicians was relevant to the patient's informed consent.

[95] *Hii Chii Kok* (n 42) [186].

[96] ibid [32]. Th is 'XKnife' procedure was described by the Singapore Court of Appeal as involving ' high-energy X-ray photon beams artificially generated by a linear accelerator, delivered in a single high dose of irradiation to the desired area of the brain. The beams are directed through a collimator, which concentrates and guides each x-ray beam in the required direction'.

[97] *Gunapath*y (n 30) [39]. Th e treatment of neurocytomas by radiosurgery at that time was largely uncharted territory.

[98] ibid [123]– [131]. The doctors only informed the patient of a five per cent risk of complications as a result of the XKnife procedure, such as brain swelling and brain damage.

brain tumour based on the facts in *Gunapathy*. Following this line of reasoning, the risks of medical AI options that have potential adverse effects on the health conditions of the patient would be material to the patient and should therefore be disclosed unless the risks or the potential harms are *de minimis.*

Where the doctor's advice is reliant on medical AI-driven diagnosis or treatment, information concerning the potentially biased or inaccurate AI outputs or training data and the opacity of AI might be relevant to a reasonable patient. This is provided that the use of medical AI would materially increase the risks of errors or uncertainties in diagnosis or treatment or the likelihood of complications. Not all cases of unexplainable medical AI warrant disclosure. Where the medical AI has been reliable in generating accurate outputs based on available external validation processes and there is no evidence of foreseeable risks of errors that can adversely affect the patient, there should not, as a general principle, be any obligation to disclose the non-explainable feature. However, the obligation is ultimately dependent on the context at the relevant time (e.g., the extent of usage of the AI and the patient's knowledge thereof).[99] The patient has the burden to show that the information is, according to peer professional opinion, material to the decision as to whether to undergo the treatment or to follow medical advice in Singapore or, in the case of Malaysia, the information is that which a reasonable patient would attach significance. In any event, when doctors are obliged to disclose the risks from medical AI, they are also entitled to share the methods they have used (e.g., external and institutional validation of AI quality and processes) to mitigate the AI-related risks and uncertainties insofar as information regarding such methods is relevant to the particular patient's health conditions.

Whilst medical AI-related information *can* be relevant, doctors must also guard against the practice of bombarding the patient with excessive technical details (such as those relating to the AI functioning and models) – a warning sounded by the Singapore Court of Appeal in *Hii Chii Kok*[100] – as that would adversely affect doctor – patient communications and would defeat the raison d'etre of informed consent.

[99] Glenn Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?' (2020) 108 *Georgetown Law Journal* 1425, 1451.
[100] *Hii Chii Kok* (n 42) [143].

III. Alternative Basis for Tortious Liability? Assessing Vicarious Liability, the Independent Contractor Defence and Non-delegable Duties

From the discussion above, the standard of care principles under the tort of negligence are sufficiently adaptable for assessing the liability of hospitals and medical doctors based on fault in the use of medical AI. They are capable of balancing the competing considerations of efficiency and innovations, and the professional and ethical responsibilities of the medical profession with compensatory justice for injured patients, even if there are aspects that are still to be ironed out. Th at said, we should also consider the liability issue from another angle. Should doctors and hospitals be ever liable in tort for the use of medical AI when there is no proof of negligence? Are there good grounds under existing tort law for making them strictly liable for errors in medical AI?

Strict liability for the tortious acts of another apply to owners of chattels who lent them to others, resulting in injuries suffered by third parties,[101] the principal for the acts of agents based on authority (whether actual or ostensible), and to persons for harms caused by ultra-hazardous activities.[102] On a prima facie level, it seems natural to consider strict liability regimes in respect of medical clinics and hospitals. Such enterprises are in a better position to insure themselves against claims by patients for medical injuries and also have deeper pockets. Organisations, especially large hospitals, have the resources to implement quality assurance programmes relating to the deployment of medical AI. As there is no strict liability (legislative) regime in Singapore pertaining to products,[103] and the product liability regime under Part X of the Consumer Protection Act 1999 in Malaysia does not extend to 'products' used in the provision of medical services,[104] this section will instead focus on whether clinics and hospitals may be strictly liable in tort in respect of the use of medical AI with reference to the existing common law doctrines of vicarious liability and non-delegable duties. From the ensuing discussion, it will be apparent that these existing doctrines are not directly applicable to determine the legal liabilities of medical doctors and hospitals in utilising medical AI. Nonetheless, the analysis below will help us explore the relevance of strict liability doctrines to medical AI and their limits.

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[101] *Morgans v Launchbury* [1973] AC 127.

[102] *Biffa Waste Services Ltd v Maschinenfabrik Ernst Hese GmbH* [2009] QB 725 [78].

[103] This is on the assumption that medical AI can qualify as products under the putative product liability system, which is not necessarily the case.

[104] Th e term 'product' under the statute refers to goods that are primarily purchased, used or consumed for personal, domestic or household purposes: see s 66 read with s 3 of the Consumer Protection Act. Moreover, s 2(2) of the statute specifically excludes healthcare services provided by healthcare professionals or healthcare facilities from its scope. See also Anisah Che Ngah, Sakina Shaik Ahmad Yusoff and Rahmah Ismail, 'Product Liability in Malaysia' in Helmut Koziol et al (eds), *Product Liability: Fundamental Questions in a Comparative Perspective* (De Gruyter, 2017) 120–46.

A. Vicarious Liability

Under existing law, the defendant may be vicariously liable for the tortious acts of the tortfeasor committed in the course of employment to the extent that it is fair and just to impose liability on the defendant.[105] Applied to the clinical setting, this means that the hospital or clinic may be legally responsible for the tortious acts of its employees even if there is no proof of any fault on their part.[106] Can the medical AI be regarded as an autonomous agent which performs a task on behalf of the clinic or hospital and be treated as an employee or akin to an employee? There are three obstacles to applying the doctrine of vicarious liability to medical AI. First, the employer's vicarious (secondary) liability can only arise where the employee is himself or herself liable under tort law. If the AI is not a legal person, it cannot be subject to tortious liability. The vicarious liability doctrine is therefore not applicable to render the hospital or doctor liable for the use of medical AI. Even if the fully autonomous AI can be regarded as a legal person,[107] there is the additional issue of whether there is any practical advantage in commencing a lawsuit against the AI for its errors since it has no assets to compensate the victim.

Second, the requirement of the existence of an employment relationship[108] between the defendant and the tortfeasor or a relationship akin to employment is far from straightforward. The hospital/doctor – AI relationship is, strictly speaking, *not* an employment relationship. But can it be argued as being akin to an employment relationship? Applying to medical AI, we observe a continuum of expertise and level of autonomy in the decision-making of AI systems. Where the medical AI applies machine learning based on the labelled data fed into the AI and carries out instructions to perform specific medical tasks, it is arguable that the relationship between the human doctor/hospitals and the AI is analogous to one of employment. The position should not change even if it is generally accepted that the medical AI can outperform human doctors in those specific tasks. Employees sometimes possess greater expertise than their employers in specific tasks. The expertise of the employee does not in itself automatically exclude him or her from being regarded as an employee for the purpose of vicarious liability.[109]

Other factors to consider would be whether: (a) the medical AI is integrated into the work processes of the clinic and hospital's provisioning of medical services; (b) control is exercised by the hospital and clinic over the data fed into the AI system and the labelling of data; and (c) there are review processes for the adoption of AI output that will form the bases for the ultimate decisions to be made by the clinic or hospital vis-a-vis their patients.

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[105] *Skandinaviska Enskilda Banken AB (Publ), Singapore Branch v Asia Pacific Breweries (Singapore) Pte Ltd* [2011] 3 SLR 540.

[106] *Gold v Essex County Council* [1942] 2 KB 293; *Cassidy v Ministry of Health* [1951] 2 KB 343; *Dr Hari Krishnan* (n 90) [111].

[107] See Belinda Bennett and Angela Daly, 'Recognising Rights for Robots: Can We? Will We? Should We?' (2020) 12 (2) *Law, Innovation and Technology* 60.

[108] Such an employment relationship is based on certain indicia, including control, integration into organisation, personal investment and contract terms.

[109] *Gold v Essex County Council* [1942] 2 KB 293, 305 (McKinnon LJ) and 313 (Goddard LJ).

Third, we need to ascertain whether the medical AI, even assuming that it can be treated as being akin to an employee, has committed a tort (e.g., negligence). In this regard, we need to answer the earlier question concerning the legal standard of care we expect from the medical AI itself. Abbott [110] suggests that if the computer is safer than humans, the new standard of care should be the reasonable computer standard based on the 'industry customary, average, safest technology'. [111] But we may legitimately question why safety should necessarily prevail over other considerations such as efficiency or accuracy. More specifically for medical AI, Chung and Zink [112] argue, on the premise that medical AI should be given a unique legal status akin to personhood, that the expected standard under medical malpractice may be analogised to that of a 'medical resident' (or similar to a medical houseman in Singapore and Malaysia). However, this standard overlooks the fact that the AI may be capable of outperforming the experienced human doctor (not to mention the medical resident) in diagnoses. Apart from the fact that the appropriate standard for medical AI itself is open to debate, such standards may be moving targets, given the fast-evolving changes and improvements in technology.

B. Independent Contractor Defence and Non-delegable Duties of Hospitals and Doctors with Respect to Medical AI

Where the hospitals and medical doctors using the medical AI will not be in a position to understand or exercise any meaningful control over the method of interpreting the data collated and processed by unsupervised machine learning, and the AI is capable of making its own rules as to how to diagnose or treat patients, medical AI may be treated as analogous to an independent contractor. In effect, the medical AI functions like a 'second doctor'. In that future scenario where the medical AI functions autonomously without any human doctors in the loop, the hospital or medical doctors should not, as a general rule, be liable for the wrongs committed by the medical AI. This is based on the independent contractor defence that one should not be responsible for the harms caused by his or her independent contractors. Additionally, it might be argued that where the hospital or medical doctor is not proved to be negligent (as discussed in the previous section) for the use of medical AI, it would be ironic to make him or her *indirectly* liable for the acts or omissions of the AI designer or software provider over whom he or she has no control.[113] The one possible exception to this is the doctrine of nondelegable duties that may be imposed on hospitals and medical doctors, which we will now examine.

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[110] Ryan Abbott, 'The Reasonable Computer: Disrupting the Paradigm of Tort Liability' (2018) 36 (1) *George Washington Law Review* 1.
[111] ibid 41.
[112] Jason Chung and Amanda Zink, 'Hey Watson: Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine' (2018) 11 (2) *Asia Pacific Journal of Health Law & Ethics* 51 .
[113] Daniel Schönberger, 'Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications' (2019) 27 (2) *International Journal of Law and Information Technology* 171.

The doctrine of non-delegable duties is distinct from vicarious liability in that the former focuses on the relationship between the defendant and the claimant rather than the defendant and the tortfeasor. The commercial reasons underpinning vicarious liability (such as employers having deeper pockets and being able to shoulder risks since they reap the benefits of the enterprise) are irrelevant to nondelegable duties as stated by the Malaysian Federal Court in *Dr Kok Choong Seng and Sunway Medical Centre Berhad v Soo Cheng Lin.*[114] A hospital and doctor may owe non-delegable duties to a patient under their care, supervision or control [115] and remain liable despite the fact that they have delegated an integral function relating to the care of the patient to an independent contractor.

Under the two-stage test in Singapore, the claimant would have to show that his or her case either: (a) fell into one of the established or recognised categories of non-delegable duties (one of which includes the hospital with regard to patients under its care);[116] or (b) possessed all of the five defining features outlined by Lord Sumption JSC in the UK Supreme Court decision of *Woodland v Swimming Teachers Association and Others.*[117] These include the vulnerability and dependence of the claimant on the defendant, the assumption of a positive duty to protect the claimant and the delegation of an integral aspect of the assumed positive duty. The ultimate decision as to whether to impose non-delegable duties on particular defendants depends on questions of fairness, justice and reasonableness.[118] The Malaysian court in *Dr Kok Choong Seng*[119] adopted a similar legal approach to Singapore to non-delegable duties with respect to hospitals.

The *Woodland* features have been specifically applied in both Singapore and Malaysia. One important feature concerns the evidence underlying the existence of an antecedent relationship and scope of a positive assumption of responsibility by the doctor or hospital towards the patient under their care and custody.[120] In *Dr Kok Choong Seng*, [121] for instance, the hospital had not assumed any positive duty to the patient as the latter reasonably expected the operation to be conducted by the medical doctor, regardless of where the operation may take place, and the hospital's role was to merely provide the relevant facilities required for the patient's admission and operation. Furthermore, as indicated in the Singapore High Court decision of *Hii Chii Kok*, the doctor or hospital may, according to the evidence adduced, be held to assume responsibility for an aspect of medical services

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[114] *Dr Kok Choong Seng and Sunway Medical Centre Berhad v Soo Cheng Lin* [2018] 1 MLJ 685 [65].
[115] *Hii Chii Kok v Ooi Peng Jin London Lucien* (n 55) [70]; *Cassidy v Ministry of Health* [1951] 2 KB 343; *cf Farraj v King' s Healthcare NHS Trust* [2010] 1 WLR (CA) 2139, where no non-delegable duty was imposed on the hospital as the patient was not in the hospital's custody or care.
[116] *Ng Huat Seng v Munib Mohammad Madni* [2017] 2 SLR 1074 [100], citing *Cassidy v Ministry of Health* [1951] 2 KB 343.
[117] *Woodland v Swimming Teachers Association and Others* [2013] 3 WLR 1227.
[118] For a criticism of the *Woodland* factors and the uncertainties generated, see Paula Giliker, 'Non-delegable Duties and Institutional Liability for the Negligence of Hospital Staff : Fair, Just and Reasonable?' (2017) 33 (2) *Professional Negligence* 109 .
[119] *Dr Kok Choong Seng* (n 114) [40].
[120] *Dr Kok Choong Seng* (n 114); *Dr Hari Krishnan* (n 90).
[121] *Dr Kok Choong Seng* (n 114) [66]. See also *Kee Boon Suan and Others v Adventist Hospital & Clinical Services (M) and Others and Other Appeals* [2018] 5 MLJ 321 [55].

(e.g., diagnosis), but not another (e.g., post-operative care).[122]

Enter medical AI. At present, in order to establish liability for breach of nondelegable duties, the patient will have to show that the AI developers and/or designers, as independent contractors, have acted without reasonable care in the development or design of medical AI, which resulted in the patient's injuries. To the extent that AI developers and designers are aware of the AI systemic responses to tasks, they should take reasonable steps to modify the algorithms to prevent anticipated harms.[123] If it is shown that the designed algorithms react to and learn from the environment and training data in unpredictable ways, the AI providers and designers may be absolved from negligence due to the lack of foreseeability of risks and expected harm.[124] It also depends on the extent to which the developer or designer knows or ought to know of the contexts in which the medical AI is put to use. As a first principle, it would be unfair to 'assign blame to the designer of a component whose work was far-removed in both time and geographic location from the completion and operation of the AI system'.[125]

In a future scenario, where the medical AI is completely autonomous and independent in its functioning, and the hospital or doctor does not have any control or review powers over the AI's decisions in pattern detections and predictive analysis, the medical AI may be analogised to an independent contractor. If so, the hospitals may in future choose to outsource certain functions (e.g., diagnosis) to the AI system as an independent contractor and only take on the responsibility to administer treatment and give medical advice to patients. However, if the human doctor remains in the loop for diagnosis, the medical AI should not be treated as an independent contractor in respect of the diagnosis.[126]

There are at least two challenges to applying non-delegable duties to medical AI, even assuming that medical AI can be regarded in law as an independent contractor. First, based on the current technology, the AI system may not be capable of taking over the responsibility for the patient's care as mentioned in *Woodland*. There is no evidence so far that AI has the ability similar to human doctors to understand and evaluate patients' preferences and values, and to communicate advice in a manner that is understandable to the patient. Th is means that the human doctor may have to be in the loop to make the ultimate decisions to advise the patient under the doctor or the hospital's care, custody and supervision.

Second, to find the hospital or medical doctor liable for breach of a nondelegable duty to the patient, it must be shown that the AI system had performed its task without

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[122] *Hii Chii Kok v Ooi Peng Jin London Lucien* (n 55) (HC) [74] (Chan Seng Onn J).

[123] Helen Smith and Kit Fotheringham, 'Artificial Intelligence in Clinical Decision-Making: Rethinking Liability' (2020) 20 (2) *Medical Law International* 1, 13.

[124] Constantine Simon (ed), *Applying Ethical Principles for Artificial Intelligence in Regulatory Reform* (Singapore Academy of Law, Law Reform Committee, Sub-committee on Robotics and Artificial Intelligence, 2020) para 2.14.

[125] Matthew Scherer, 'Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies' (2016) 29 (2) *Harvard Journal of Law & Technology* 353, 372.

[126] The AI system is currently also not 'independent' in terms of the capacity to conduct a business on its own account. Hence, it cannot be treated as a legal person capable of owning assets, or suing and being sued on its own account.

reasonable care. Similar to the case for vicarious liability, there is therefore a need to determine the appropriate legal standard of care expected of the medical AI. We have already discussed in section II above the difficulties in selecting the criteria for determining the standard in the face of the evolving AI technology.

IV. Conclusion

Tort law needs to keep abreast of the developments in medical AI in the healthcare sector. Analogies may be drawn from existing common law case precedents generally as a starting point for application to medical AI. These legal rules and principles, together with public policy, as applied to the contexts in Singapore and Malaysia should have further resonance in the wider common law world as it starts getting to grips with the emerging AI technology in the delivery of healthcare services.

The robustness of a legal doctrine may be subject to stress tests in novel cases. Given the intrinsic nature and historical evolution of the doctrine of negligence beginning with *Donoghue v Stevenson*,[127] it is certainly not anathema to but is capable of embracing future changes. A tentative argument may be made that the standard of care principles in the common law tort of negligence provide a fault-based framework that is sufficiently flexible to accommodate the use of AI innovations in healthcare and to deal with the challenges posed as the technology continues to develop. The process of determining the appropriate standard of care allows for a judicious balance amongst the competing considerations: the efficiency and benefits generated by medical AI, encouraging the adoption of AI innovations by doctors and hospitals, granting injured patients compensation for the harms that have been caused by the negligence of the doctors or hospitals if they can prove fault, and taking into account the ethical responsibilities of the medical profession and patient well-being.

[127] *Donoghue v Stevenson* [1932] UKHL 100.