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ENSURING PRIVACY AND PERSONAL DATA PROTECTION IN MATTERS ARISING FROM BIOPRINTING: ADDRESSING THE HUMAN AND SOCIAL CONTEXT OF BIOMEDICAL INFORMATICS IN MALAYSIA

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Abstract: *The advent of bioprinting raises the issue of patients' privacy and personal data protection as health data and information are involved, especially through images obtained and analysed via Magnetic Resonance Imaging (MRI) and Computer Tomography (CT) scans that are turned into a digital file and subsequently printed as a model or replica of the patient's organ. This not only involves imaging informatics that form the larger part of Biomedical Informatics (BMI) but also Ethical, Legal and Social Issues (ELSI) such as informed consent, secondary use of data, confidentiality, and privacy — all of which constitute the fourth corollary of BMI, i.e. in the human and social context. Belgium and Germany are exemplary countries whose privacy and personal data protection laws have been analysed to adequately address issues that arise from bioprinting. Therefore, this study sets out with the objective of analysing current personal data protection issues that arise with the dawn of bioprinting in Malaysia on the basis of the country's Personal Data Protection Act 2010 (PDPA 2010). The methodology of this study is qualitative, relying on a doctrinal research approach towards interpreting the Malaysian, Belgian and German laws on privacy, personal data, and one relevant case law. A socio-legal approach is also applied because this study is multidisciplinary, combining law and biomedicine. A socio-legal approach is also relevant because both textual and content analyses as well as interview (as methods of gathering data and analysis used in the social sciences) have been utilized. The results from this study indicate that Malaysia's PDPA 2010 contains sufficient provisions for Prior Informed Consent (PIC) from a patient, safeguards the right of a patient to withdraw his data or request that they be altered or erased, and permits a patient's health data to be utilized for reasons beyond their original purpose. Unlike the Belgian Privacy Act of 1992, Malaysia's PDPA 2010 does not permit a patient's health data to be used for insurance and social security purposes. The PDPA 2010 also has a provision which permits a patient's data to be processed*

for generating statistics that could be useful for scientific and educational research. The Personal Data Protection Standard 2015 also recommends a non-disclosure agreement in the form of a contract between the data user and data processor so as not to divulge a patient's health data, much like the Belgian Privacy Act.

Keywords*: Personal Data Protection Act 2010 (PDPA 2010), bioprinting, Malaysia, Prior Informed Consent (PIC), Germany, Belgium*

Introduction

Bioprinting has made its mark on Malaysian shores. It has been defined as "the spatial patterning of living cells and other biologics by stacking and assembling them using a computer-aided layer deposition approach to develop living tissue and organ analogs for tissue engineering, regenerative medicine, pharmacokinetic, and other biological studies" (Ozbolat, 2015, p. 395). This technology, once matured, holds promising prospects for the sciences and medicine, and can benefit Malaysian society at large, especially in replacing internal organs, skin and broken bones as part of reconstructive surgery and regenerative medicine. These are just a few of the prospects that bioprinting holds, but like any newly introduced technology, there are ethical and legal implications. One of the arising issues concerns a patient's given health data through Magnetic Resonance Imaging (MRI) and Computer Tomography (CT) scans which are then turned into a digital file, and subsequently printed as a model or replica of the patient's organ. This certainly involves imaging informatics which focuses on tissues and organs by utilizing applications such as the CT scanner and software algorithms to produce a three-dimensional image of human organs (University of South Florida, 2018). In turn, imaging informatics is part of the scope of the broader biomedical informatics (BMI) (Kulikowski et al., 2012, p. 933). BMI has been defined as the "interdisciplinary field that studies and pursues the effective uses of biomedical data, information and knowledge for scientific inquiry, problem solving and decisions making, driven by efforts to improve human health" (Kulikowski et al., 2012, p. 933). Indeed, Moore and Holmes (2016, p. 2) have pointed to the critical role that visualization derived from imaging informatics and the novel technology of 3D printing could play, which could revolutionise biomedical informatics. Thus, bioprinting that relies on imaging informatics can contribute to the broader integration of biomedical informatics.

All patient inputs are considered information, thereby raising the matter of privacy and personal data protection. Associated with the matter of personal data protection is the need to obtain Prior Informed Consent (PIC) from the patient to gather his/her data, explaining the reason for gathering such data, the right of the patient to withdraw his/her PIC at any time, the possibility for such data to be altered or erased, as well as permitting the data to be used for marketing, health insurance and social security purposes beyond the original reason for gathering them. All these aspects have raised the fourth corollary of BMI as emphasized by Kulikowski et al. (2012, p. 935), namely, the human and social context for evaluating policies, and the evolution of economic, ethical, social and organizational systems. Ethical, Legal and Social Issues (ELSI) such as the human subject, informed consent, secondary use of data, confidentiality and privacy are part of the fundamental knowledge to be acquired in the human and social context by the fourth corollary of BMI (Kulikowski et al., 2012, p. 935). Therefore, this study's focus on patient privacy and personal data protection from a legal standpoint in the context of bioprinting in Malaysia is very timely in addressing the fourth corollary of BMI, as this remains an underexplored area.

Currently, few scholarly literatures have examined how the Belgian privacy law and German personal data protection law are affected by the advent of bioprinting (Mihalyi & Müller, 2016;

Vinck et al., 2018). However, such a step is yet to be attempted with respect to the Malaysian context.

Therefore, this study has the objective of analysing current personal data protection issues that arise with the advent of 3D bioprinting in Malaysia, based on the country's Personal Data Protection Act 2010 (PDPA 2010) as well as a previous case law prior to this legislation. Such effort should shed light on whether Malaysia is ready to address privacy and personal data protection issues that arise with the dawn of bioprinting in this country.

Literature review

The advent of bioprinting involving the processing of a patient's health data from images of CT or MRI scans so as to create 3D design models of organs or other tissues certainly raises personal data protection issues for patients. Daly (2018), Li and Faulkner (2017), Mihalyi and Müller (2016) as well as Vinck et al. (2018) have raised the need for countries to review their laws on privacy or personal data protection to ensure that these regulations can adequately support arising personal data issues specifically associated with the dawn of bioprinting.

Mihalyi and Müller (2016), in reviewing the German Federal Data Protection Act (*Bundesdatenschutzgesetz*), have insisted that MRI and CT scans containing information about the surface structure, shape and volume of a patient's tissue are information within the said German law. The printing of a new organ in section 3(1) of the German Federal Data Protection Act is considered new personal data that has been processed (Mihalyi & Müller, 2016, pp. 1640–1641). Moreover, these researchers (Mihalyi & Müller, 2016, p. 1641) indicate that a printed organ under German law becomes information by virtue of being maintained, stored or used for other purposes.

In considering 3D bioprinting in the United Kingdom (UK), privacy issues raised include adequate protection of the patient's data by means of the Computer Aided Design (CAD) software, the patient's consent in utilizing his/her health data, and using the patient's data for direct marketing, health insurance, social security, and other purposes (Cantreau, 2016).

As to the Belgian Privacy Act on the protection of privacy in relation to the processing of personal data (1992, henceforth Belgian Privacy Act), some of the pertinent issues raised include professional secrecy by the healthcare provider in releasing a patient's personal data to third parties (outsource manufacturer, other healthcare and non-healthcare professionals) (Vinck et al., 2018, p. 95). Of significance is the Belgian Privacy Act's stress on signing a contract containing a confidentiality clause wherein healthcare professionals including physicians, nurses, paramedics, certain administration personnel and technical engineers are bound by the legal duty of professional secrecy not to reveal the patient's health data (Vinck et al., 2018, p. 96). Liability of the data processor and further processing of a patient's data for scientific research through anonymization or encoded data, marketing, health insurance and social security purposes are also addressed by the Belgian Privacy Act (Vinck et al., 2018, pp. 96-97).

Previously, bioprinting was analysed in the context of Malaysia's Strategic Trade Act 2010 (STA 2010), particularly with regard to Intangible Technology Transfer (ITT) but never within the ambit of the PDPA 2010 (Majid, 2016). As scholars have now begun to analyse other countries' laws on privacy and personal data protection in connection with 3D bioprinting, this study's effort to embark on the same path with regard to Malaysia's PDPA 2010 is therefore timely, especially with respect to issues arising from bioprinting. If this is not the case, there would be a need to amend the law in order to incorporate some of the missing aspects. To the best of one's knowledge, such a study in relation to Malaysia's PDPA 2010 and matters arising from bioprinting is still lacking.

Methodology

This study is qualitative, while its socio-legal approach is relevant as this study cuts across multiple disciplines such as law and biomedicine. Since the typical social science methods of textual and content analysis are being used in this study, it further justifies the choice of a socio-legal approach. A doctrinal research approach is applicable to this study because provisions from the 1992 Belgian Privacy Act, the German Federal Data Protection Act, Malaysia's PDPA 2010, as well as one case law are all being analysed and interpreted through a textual analysis in the context of bioprinting. To an extent, this is also a comparative study because it compares the 1992 Belgian Privacy Act, the German Federal Data Protection Act, and Malaysia's PDPA 2010 on certain personal data issues.

A content analysis of books, journals, newspaper articles, and other relevant information obtained from the internet, all secondary resources of course, was carried out in this study to provide an overview of the background to bioprinting and personal data protection within the context of role-model countries such as Belgium and Germany. A content analysis was also applied to analyse the data obtained from an interview with Malaysia's Ministry of Communications and Multimedia, which was conducted on July 6th, 2018. The accuracy of the interview data was verified by the respective officer in the Personal Data Protection Department (PDPD) of the said Ministry before being utilised in this study.

Bioprinting's Process and Utilisation

Bioprinting creates living tissues by extruding cells using a bioprinter which builds biological structures, layer by layer. The bioprinter itself is a robotic dispersing device that puts biomaterial living cells or tissue spheroids and rods in precision, based on a digital model. Living cells are harvested from humans and are sufficiently cultivated to create bio ink which is then loaded to a bioprinter.

MRI or CT scans are then used to scan a specific patient's body parts or organs. With the scanned image of the body part or organ, and aided by a Computer Aided Design (CAD) software, a model or replica of the patient's organ is then printed. The bio ink not only contains a patient's cells but also an organic or synthetic glue, normally a dissolvable gel known as a collagen scaffold or other types of support that enable the cells to attach themselves and grow. The cells deposited by the bioprinter would then mould, stabilize, and grow into the correct form.

Cells that are bio printed have the capacity to assume the correct positioning among themselves even without the scaffolding because they have inherent properties that allow them to seek and match each other. Currently, there are many different methods on the market that use bioprinters to deliver the bio ink through extrusion, laser, microvalves, inkjet, or tissue fragment printing.

The current state of the art for bioprinting merely permits the development of organs and tissue constructs that do not require substantial vascularization, and mini tissue models that imitate the biology of their natural counterparts to enable pharmaceutical testing or cancer studies. Among some worthy achievements worth mentioning are the use of human tissue for the creation of artificial human skin, the experimental process of producing kidneys, livers, intestinal segments, bones, ears, and heart valves (Galamas, 2015, p. 8; Lindstrom, 2014, p. 2; McNulty, Arnas & Campbell, 2012, p. 3). Printable vaccine, currently under experimentation, in order to provide a much needed cure for diseases fastidiously in any part of the world through the sending of digital files over the internet will also make its mark someday (Riedmann, 2012, p. 1744). Dr. Anthony Atala of Wake Forest

University, United States (US), used bioprinting to create a two-chamber heart that is still in its experimental stage, a kidney, and printed human skin (McNulty, Arnas & Campbell, 2012). This has led to an industrial partnership with Lexmark and Organogenesis Incorporated to create a portable skin printing device for printing skin in the battlefield (McNulty, Arnas & Campbell, 2012, p. 9). In another case, a German laboratory has printed sheets of heart cells that can be used to repair damage from a heart attack (Galamas, 2015, p. 9). In 2014, doctors in the Netherlands replaced a patient's damaged skull with a plastic one using bioprinting technology (Zaleski, 2015, p. 2). Likewise, in 2015, a patient in Spain was implanted with a 3-D printed titanium sternum and rib cage to replace bones as doctors excised a tumour (Zaleski, 2015, p. 2). In 2006, Professor Lipson at Cornells' Creative Machines Lab used bioprinting to print cartilage for a patient with knee injury (Sethi, 2015). Invetech and Organovo have also created bioprinters to print human tissues (Galamas, 2015, p. 8). In China, scientists have used bioprinting to print blood vessels from stem cells successfully and then transplanted them into rhesus monkeys ("Chinese scientists", 2016, p. 1). 3D Bioprinting Solutions from Russia have also successfully implanted a 3D thyroid gland into a mouse ("Chinese scientists", 2016, p. 3). Indeed, the long-term goal of bioprinting is to bring positive developments for the human race by producing organ replacements due to shortages and difficulty in procuring the necessary. Despite these promising developments, it may still take considerable time before scientists are able to build solid organs such as the heart and liver, as it involves different cells as well as overcoming the problem of vascularization. Therefore, bioprinting still requires substantial development before any of the developed organs can be rendered safe to be implanted into humans in the foreseeable future.

Apart from printing real tissues and organs, bioprinting already produces models that replicate a patient's internal organ. Such models are used by surgeons to simulate complicated surgeries prior to actual surgery in the operation theatre and to provide a useful guide for the step-by-step process.

Having provided an overview of bioprinting developments worldwide, the following section will take a closer look at bioprinting's progress in Malaysia.

Introduction of Bioprinting in Research Institutions, Universities and Industry in Malaysia

In Malaysia, bioprinting has only been embraced by its scientists from research institutions, universities, and the industry. In MediTeg at the University Technology Malaysia (UTM), scientist Saiful Izwan Abdul Razak is in the process of producing a blood vessel which is anticipated to be later used for coronary heart surgery ("Mencetak organ", 2017, p. 2). MediTeg is also in the process of coming up with a facility to bioprint skin for skin replacement from burns and pimple scars ("Mencetak organ", 2017, p. 2). Similarly, research has been done to evaluate fibrin-gelatin as a hydrogel for bioprinting skin by the University of Malaya (UM) (Hakam, Imani, Abolfathi, Fakhrzadeh & Sharifi, 2016).

Besides these, foreign companies with expertise in 3D bioprinting have also made their debut by setting up facilities in Malaysia. One such effort was by Materialise which enabled a doctor at the Pantai Medical Hospital, Kuala Lumpur, to use virtual surgical planning and 3D printed surgical guides to assist in the repositioning of a patient's arm bone which had been fractured (Park, 2013, p. 2). To accomplish this task, a CT scan of the patient's arm was utilized in the virtual 3D reconstruction of the patient's bone (Park, 2013). Stratasys 3D printing technology has also been introduced at the Centre for Biomedical and Technology Integration (CBMTI), UM, for the creation of custom biomodels for research and surgical training (Kumar, 2013, p. 1). In another development, a specialist at the Tuanku Mukhris Hospital, National University of Malaysia (UKM), collaborated

with Materialise in using virtual surgical planning and 3D printed surgical guides to reconstruct a skull for a patient with a fractured skull from a car accident; the patient underwent skull reconstruction surgery ("Implan wajah", 2015, p. 2). In fact, at the Tuanku Mukhris Hospital, UKM, the first transplant in Malaysia of a custom-made 3D-printed titanium implant, mimicking a real bone into a female patient with a fractured skull took place (Lee, 2015, p. 3). To enable the production of a 3D-printed titanium implant, it involved the patient's MRI and CT scan, plus a CAD specialized 3D software (Lee, 2015, p. 3). The virtual surgical planning, 3D printed surgical guides, and printed titanium implant obviously involved outsourcing to a processor capable of doing what is necessary. Thus, a collaborative effort has come about between a doctor in UKM and a team of clinical engineers from a subsidiary company of Materialize called OBL (Lee, 2016, p. 3). Pebblereka 3D Print, a company in Malaysia, has also managed to produce a prostatic hand for a little girl who was born without one of her hands so as to enable her to lead a normal life (Alaui, 2015, pp. 1-2).

As for Malaysia's position in promoting 3D printing more broadly, MIMOS Berhad, Malaysia's leading institution for research on microelectronics, has signed a Memorandum of Understanding (MoU) with Autodesk for an initiative called the 3D Smart Maker Initiative (Saunders, 2016). This initiative is expected to establish 3D printing facilities throughout Malaysia and encourage small business entrepreneurs to utilise this technology as they see fit (Saunders, 2016). One of the first 3D printing labs was launched at the PERDA Advanced Technical Institute (PERDA-TECH) in Penang, Malaysia, in November of 2016, which was based on a cooperative relationship between MIMOS Berhad and Autodesk ("MOSTI's first", 2016, p. 1).

Based on the above developments, there is no doubt that bioprinting and 3D printing have broadly made their presence in Malaysia felt. But along with these developments, the time is also ripe to start thinking long and hard about privacy and personal data protection, especially as this technology becomes more widely used in Malaysia and other countries, to which we now turn.

Bioprinting and Personal Data Protection in Selected Countries

Belgium

The Belgian Privacy Act has incorporated the European Union's (EU's) Personal Data Protection Directive (PDPD) regarding "processing personal data" and "controller" (Vinck et al., 2018, p. 95). Article 2(b) of the PDPD regards a patient's personal health data as "processed" if it is subjected to operations (not necessarily through automation means) such as collection, recording, storage, organization, alteration, retrieval, adaptation, use, consultation, disclosure by transmission and dissemination. Furthermore, "processing" according to article 2(b) of the PDPD may refer to making available, alignment or combination, blocking, erasure or destruction of a patient's personal health data. The Belgian Privacy Act has also adopted the definition of a "data controller" in article 2(d) of the PDPD:

> *"the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; (...)".*

With regard to the meaning of "processing" in the context of bioprinting in the Belgian Privacy Act, it is assumed that without anonymization, a patient's 2D scans, his condition or behaviour, CAD, as well as the patient's specific model or medical device produced via bioprinting can be considered personal data under Belgian law (Vinck et al., 2018, p. 95). As for the role of the controller, this would be the role of the hospital whilst the processor would refer to the external

outsource manufacturer assigned with the task of bioprinting in accordance with the Privacy Act (Vinck et al., 2018, p. 95).

Besides the above, other aspects of the Belgian Privacy Act relevant to the issue of bioprinting include the legitimate basis for embarking on bioprinting in Articles 4, 7 and 20, the duty to inform the data subject about the bioprinting procedure as in Article 9, and the right of rectification and access to the patient's or subject's data as indicated by Articles 10 and 12 (Vinck et al., 2018, p. 97). Additionally, outsourcing bioprinting to a processor is covered by Article 16, the controller's liability by Article 15 *bis*, and notification to the supervising authority by Article 17 of the Belgian Privacy Act.

Accessibility to a patient's health data is also another pertinent issue in the Belgian Privacy Act. Staff who have access to a patient's health data may include physicians, nurses, paramedics, certain administrative personnel, and technical engineers who are part of the hospital's medical team. This group of people are bound by the legal duty of professional secrecy not to divulge a patient's health data as long as they are involved in the patient's treatment, act in the therapeutic interest of the patient, and withhold information where necessary. As for the outsourced processor, Article 7, Section 4 of the Belgian Privacy Act stipulates that a patient who has given written consent for the processing of his health data to the outsourced manufacturer (or data is processed to prevent an imminent danger) exempts the controller from the responsibility of ensuring that a patient's data is processed by a healthcare professional. Moreover, Article 16, Section 1, 3° of the Belgian Privacy Act stresses the need for a mandatory contract that incorporates a confidentiality clause and determines the liability of the processor towards the controller.

In terms of whether a patient's health data can be utilized for other purposes besides bioprinting, this is permissible, e.g. for scientific research according to Articles 2 to 24 and Articles 28 to 31 of the Belgian Privacy Act, provided there is anonymization of the data. If data anonymization is not possible, this can be accomplished by encoding the data. A patient can object to the processing of his health data for marketing purposes, provided that the controller informs him no later than the date of data acquisition. And if the data is not directly obtained from the data subject, the objection should be made no later than the date when the data is provided to a third party or used on behalf of a third party in accordance with Article 9, Section 1 (c) and Section 2 (c) of the Belgian Privacy Act.

As for health insurance purposes, the processing of a patient's health data is permissible for the sake of complying with social security laws even without patient consent in conformance with Article 7, Section 2 (c) of the Belgian Privacy Act.

Hence, this discussion has touched upon various issues arising from bioprinting in relation to patient health data protection within the ambit of the Belgian Privacy Act.

Germany

Mihalyi and Müller (2016, p. 1639), in their analysis of Section 3 (1) of the German Federal Data Protection Act, have indicated that a patient's MRI or CT scans, referring to information about the surface structure, shape and volume of a patient's tissue which are to be replicated to create a model, fall within the definition of *Einzelangabe*. *Einzelangabe* is defined as "the personal or material circumstances of an identified or identifiable individual" (Mihalyi & Müller, 2016, p. 1639). As such, it raises confidentiality and personal data protection issues regarding a patient's health data in connection with bioprinting.

With regard to a printed organ, Mihalyi and Müller (2016, p. 1640) indicate that this can be considered as new personal data and as the outcome of processing within Section 3(1) of Germany's Federal Data Protection Act. The initial patient's data from the MRI or CT scans are processed and altered, generating new data in the form of a printed organ. The newly printed organ now contains genetic and cellular properties following the exact shape and structure provided by a patient's CT or MRI scans. The printed organ can also be regarded as information by virtue of its digital data which is stored and maintained with its intentional use in line with the German Federal Data Protection Act (Mihalyi & Müller, 2017, p. 1641).

Based on the aforesaid examples of Belgium and Germany, it is clear that their personal data protection or privacy laws are capable of addressing various issues arising from the introduction of bioprinting. The following section will examine Malaysia's PDPA 2010 as to whether it is equally capable of addressing the issues stemming from bioprinting as exemplified by the examples of Belgium and Germany.

Personal Data Protection Issues Arising from Bioprinting in Malaysia

To create a 3D implant that is custom-made to a patient, it involves the electronic processing of the patient's data. A patient's two dimensional (2D) medical imaging from CT scans will be converted to 3D imagery. In this regard, other useful patient data will be used simultaneously such as information that pertains to the patient's condition or behaviour. The created 3D images will subsequently be edited by the physician (radiologist or surgeon) and engineers using the CAD software in accordance with the instruction from healthcare professionals. Next, the CAD file will be uploaded to a 3D printer to print a medical device or model reflecting the patient's morphology. All steps involved in 3D printing incorporate data relating to the patient's health status, and this is regarded as highly sensitive data.

In Malaysia, the PDPA 2010 merely applies to private rather than government hospitals. Only certain statutory bodies which discharge regulatory functions are bound by the PDPA 2010 but with partial exemption on the application of the seven principles (Personal Data Protection Department (PDPD), 2018). For government hospitals, they are bound by the Ministry of Health's own guideline on the protection of patient's personal data from any breaches and the need to obtain the patient's prior consent (PDPD, 2018).

Moreover, the surgeon who takes charge of how a patient's CT scan or 3D images are to be altered by an engineer from an outsourcing company that produces the 3D guide, model or implant can be regarded as a data user according to the PDPA 2010. Section 4 of the PDPA 2010 defines such data user as "a person who either alone or jointly or in common with other persons processes any personal data or has control over or authorizes the processing of any personal data, but does not include a data processor". The patient who provides CT scans of his body parts to be subsequently processed as 3D imagery is considered a data subject in Section 4 of the PDPA 2010 and is known as "an individual who is the subject of the personal data". The company responsible for processing the patient's data, as in the CT scan which utilizes a CAD software and receives relevant instructions from the surgeon, can be regarded as a data processor under Section 4 of the PDPA 2010. A data processor with regard to personal data refers to "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" (PDPA 2010). Indeed, the patient's scan, information pertaining to the patient's condition and behaviour in the CAD files, the patient's specific model or medical devices produced on the basis of the integrated information that identifies the patient

uniquely through a name tag or code can all be regarded as sensitive personal data. Section 4 of the PDPA 2010 indicates that sensitive personal data "[consist] of information [pertaining] to the physical or mental health or condition of a data subject […]". This is broad enough to encompass the various aspects involved in 3D bioprinting mentioned above.

If a company has been tasked by a surgeon with processing a patient's CT scan to be converted to 3D images and to be subsequently altered according to specific instructions, this is regarded as processing. Section 4 of the PDPA 2010 refers to processing as "collecting, recording, holding or storing the personal data or carrying out an operation or set of operations on the personal data, including:

a) The organization, adaptation or alteration of personal data;
b) The retrieval, consultation or use of personal data;
c) The disclosure of personal data by transmission, transfer, dissemination or otherwise making available; or
d) The alignment, combination, correction, erasure or destruction of personal data".

It is apparent that the communication and instructions between the surgeon and company tasked with producing the 3D model or medical device clearly involve consultation on the use, adaptation or alteration of a patient's personal data, all of which will be reflected in the final product.

Section 40(1)(a) and (b)(iv) of the PDPA 2010 indicates that a surgeon (data user) cannot process any sensitive personal data unless the patient (data subject) has given his explicit consent to use such data for medical purposes only. Section 40(4) defines the scope of "medical purposes" in terms of preventive medicine, medical diagnosis, medical research, rehabilitation, provision of care and treatment, and the management of healthcare services. If a 3D bioprinting implant is used for the treatment of a patient, it clearly falls within the scope of medical purposes. A foreign company like Materialise, with a branch office in Malaysia and is clearly involved in 3D bioprinting processing, is also bound by the PDPA 2010 because Section 2(4)(d)(i) covers "any person [who] maintains in Malaysia […] an office, branch or agency through which he carries [out] any activity". In the case of a data processor (e.g. a company like Materialise involved in bioprinting but with a base in Belgium) that necessarily transfers and further processes a patient's health data back in its home country as facilities in Malaysia may be inadequate, this is permissible under Section 129(3) of the PDPA 2010 which is quoted below:

"Notwithstanding subsection (1), a data user may transfer any personal data to a place outside
Malaysia if—
(a) the data subject has given his consent to the transfer;
(b) the transfer is necessary for the performance of a contract between the data subject and the data user;
(c) the transfer is necessary for the conclusion or performance of a contract between the data user and a third party which—
(i) is entered into at the request of the data subject; or
(ii) is in the interests of the data subject".

With regard to a contract between the data user and data processor on the confidentiality of patient data, the Personal Data Protection Standard 2015 requires that the data processor enters into an agreement with the data user to ensure that a patient's data is secured and no breaches occur (PDPD, 2018). Failure to comply with this requirement is an offence and upon conviction is liable

to a fine not exceeding RM 250,000 (US$ 61538.75) or imprisonment for a term not exceeding two years or both fine and imprisonment to run concurrently (PDPD, 2018).

Moreover, Malaysia's User Access Control Policy and Guidelines stresses that "[c]are providers are bound by the Code of Ethics of their profession regarding the confidentiality of patient information" (Ministry of Health, 2011, p. 6). This Guideline is applicable to government hospitals. It has also been asserted that "[a]ll persons involved in the care of the patient and in the management of the data are responsible for the confidentiality of the patient's clinical information" (Ministry of Health, 2011, p. 6). The phrase "all persons" can be assumed to cover the processor, i.e. the outsourced company charged with producing the 3D images and models. Indeed, the User Access Control Policy and Guidelines (Ministry of Health, 2011, p. 7) also acknowledges that the PDPA 2010 would also apply to all healthcare facilities, even those in the private sector. Additionally, the User Access Control Policy and Guidelines (Ministry of Health, 2011, pp. 6-7) complements the Malaysian Medical Council (MMC) Ethical Codes and Guidelines that outlines the professional conduct and duties of a doctor in terms of good medical practices and ensuring patient confidentiality. Despite all this, the aforesaid Guidelines is non-binding.

Of great significance to 3D bioprinting involving patients who provide their health data is the need for a Prior Informed Consent (PIC). In this context, Section 40(1)(a) clearly indicates that the patient (data subject) should have "given his explicit consent to the processing of the personal data". Regulation 3 of the Personal Data Protection Regulation stipulates that the consent given must be recorded and maintained which can be in the form of writing or kept in a database system (PDPD, 2018).

In the case of *Lee Ewe Poh v. Dr. Lim Teik Man & Anor* (2010, hereafter *Lee Ewe Poh*), it clearly shows that a written consent is needed from the patient. In this case, the doctor took photographs of a female patient's private part (i.e. anus) during a stapler haemorrhoidectomy operation while she was unconscious (*Lee Ewe Poh*, 2010). In this situation, the judge decreed that "written consent is preferred in relation to obtaining of clinical images" (*Lee Ewe Poh*, 2010, p.7). Furthermore, it was also stated that "written consent is to be obtained ideally in particular that the written consent should include an explanation of the need for and purpose of such documentation, or that the images will form part of their confidential health records […]". The judge also indicated the form of images that need PIC, namely "[c]onsent to x-rays and ultrasound investigations are [to be] given implicitly by the patient undergoing those procedures" (*Lee Ewe Poh*, 2010, p. 6). Moreover, it was further elaborated that "by [being present] for treatment and investigation, the patient enters into a tacit agreement to documentation, which includes images as well as written information" (*Lee Ewe Poh*, 2010, p. 6). Obviously, any images taken even in the form of x-rays and ultrasounds would require a PIC based on the judgement in this case.

While the judgment on the *Lee Ewe Poh* (2010) case involving privacy, rights was passed much earlier before the PDPA 2010 came into force in 2013, it certainly sets a precedence and much can be learned from it. Going back to the CT scans and 3D bioprinting images, these would then form part of the patient's health record that would require a written PIC following the *Lee Ewe Poh* (2010) case. In any case, Section 40(1) (a) of the PDPA 2010 requires that the patient must first agree by way of an "explicit consent to the processing of the personal data".

Another issue of concern with regard to the patient's data in 3D bioprinting concerns security. Section 9(1) of the PDPA 2010 indicates that a data user "when processing personal data, takes practical steps to protect the personal data from any loss, misuse, modification, unauthorized or accidental access or disclosure, alteration or destruction […]". Additionally, Section 9(2)(a) and

(b) of the PDPA 2010 also requires a data processor, in this case companies entrusted with the responsibility of processing a patient's data, to provide sufficient technical guarantee and organizational security measures governing the processing to be carried out and take reasonable steps in complying with those measures. While a government hospital which utilizes the services of a private company for bioprinting purposes may not be bound by the PDPA 2010, the company concerned will still be bound by the security measures stipulated in this law. On the other hand, a doctor in a private hospital as data user and the processor are both bound by security measures to be taken in accordance with Section 9 of the PDPA 2010. In *Lee Ewe Poh* (2010, p. 8), the judge cautioned that photographs of the patient's private part stand in danger of being released to the public domain because "[i]n the present advance technology any information could have come to the public domain if there is no proper security or safeguard to protect such information from misuse". Thus, it stands to reason that the PDPA 2010 has already incorporated security measures to be implemented as discussed.

With regard to using the patient's personal data for research purposes besides those disclosed at the time of collection, the PDPA 2010 in Section 45 (2) (c) addresses this issue. Section 45 (2) (c) states that a patient's data can be "processed for preparing statistics or carrying out research [which] shall be exempted from the General Principle, Notice and Choice Principle, Disclosure Principle and Access Principle and other related provisions of this Act, provided that such personal data is not processed for any other purpose and that the resulting statistics or the results of the research are not made available in a form which identifies the data subject". Thus, the PDPA 2010 has a provision that enables a patient's data to be processed for research statistical purposes, which may be useful for scientific and educational research. In the *Lee Ewe Poh* (2010, p. 6) case, the judgment indicated that "if such an image is subsequently to be published, or used for educational research, written consent must be sought for that specific purpose".

Besides, under Section 43(1) of the PDPA 2010, a patient (data subject) has the right to prevent processing for purposes of direct marketing. Specifically, Section 43(1) of the PDPA 2010 indicates that a patient "at any time by notice in writing to a data user, [may] require the data user at the end of such period as in reasonable in the circumstances to cease or not to begin processing his personal data for purposes of direct marketing". This is similar to the Belgian Privacy Act in Article 9, Section 1(c) and Section 2(c), stipulating the time frame when a patient can object to the processing of his health data for marketing purposes.

In cases whereby, a patient may decide to withdraw a PIC for the processing of his personal data, this is addressed in Section 38(1) and (2) of the PDPA 2010. A written notice stating withdrawal of a patient's consent to process his personal data is needed in accordance with Section 38(1) of the PDPA 2010. Upon reception of this notice, the data user (surgeon or healthcare professional) will have to cease processing the patient's personal data for 3D bioprinting in line with Section 38(2) of the PDPA 2010. With regard to the patient altering his personal health data if it is inaccurate, Section 34(1) (b) indicates that a patient can request in writing that the necessary corrections be made to his personal health data if it is known that "his personal data being held by the data user is inaccurate, incomplete, misleading or not up-to-date". Section 35(1)(a) and (b) of the PDPA 2010 then obliges the data user to correct the patient's personal health data and provide a copy of the corrected version to the patient.

Additionally, with the development of 3D bioprinting in Malaysia, it stands to reason that the Commissioner who oversees the PDPA 2010 would make inquiry into the progress of this technology. Section 48(f) of the PDPA 2010 enables the Commissioner "to undertake or cause to be undertaken research into and monitor developments in the processing of personal data, including technology, in order to take account [of] any effects such development may have on the privacy of

individuals in relation to their personal data". This provision should be utilized by the Commissioner to perhaps commission a study on how 3D bioprinting would impact patients' personal data, especially in the healthcare sector.

In sum, this section has highlighted the provisions of the PDPA 2010 that would be of relevance to 3D bioprinting in Malaysia as this technology becomes more widespread.

Conclusion

This study sets out with the task of analysing current personal data protection issues that arise with the advent of 3D bioprinting in Malaysia, based on the country's PDPA 2010. Overall, Malaysia's PDPA 2010 contains adequate provisions that are more than capable of addressing matters that may arise with the dawn of bioprinting in the country, since it covers the need to obtain a PIC from the patient, the right of the patient to withdraw a PIC at any time, the ability to be able to alter or erase the data, as well as permitting a patient's health data to be used for marketing purposes beyond its original aim. The Personal Data Protection Standard 2015 also recommends a non-disclosure agreement in the form of a contract between the data processor and data user not to divulge a patient's health data. The PDPA 2010 also contains a provision that permits a patient's data to be processed for generating statistics and thus exempt from certain principles within this law which would be useful for scientific and educational research. Besides, the PDPA 2010 does not permit a patient's health data to be utilized for insurance and social security purposes, unlike the Belgian Privacy Act.

Thus, it can be concluded that Malaysia is ready legislatively to address any personal data protection matters which may arise with the advent of bioprinting, just as in the cases of Belgium and Germany that have been highlighted in this study. By fulfilling these requirements, Malaysia has also met the ELSI of bioprinting which addresses the human and social context of BMI that makes up the fourth corollary.

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