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STEM CELL TECHNOLOGY IN MALAYSIA: ADDRESSING THE ETHICAL MISCONDUCTS IN PURSUANT OF SCIENTIFIC RESPONSIBILITY

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SUMMARY

Stem cell (SC) technology in Malaysia is progressing but currently overlooked by the Guideline for Stem Cell Research and Therapy 2009. In the last decade, no law or policy was enacted specifically to regulate the technology. Hence, this study aims to explore the ethical and regulatory issues of Malaysian SC technology in pursuant of scientific responsibility. The in-depth interview (IDI) of SC policymakers and literature review revealed that SC remains unregulated and triggering serious ethical problems, which without official complaint from public remain unresolved. It is a significant study, as it presents a broad understanding of SC regulation in Malaysia.

1.0 Introduction

Tissue engineering and regenerative medicine (TERM) are two medical disciplines that complement one another [1-2]. While research in this area is improving, the unique regenerative ability of stem cell (SC) is revolutionizing TERM [3-4]. Since SC is extracted from many human sources and involves human subjects, there are many areas with considerable concern. Studies have highlighted that while the unintentional destruction of embryos during SC extraction as most controversial, the unproven SC therapies, exploitation of women egg donors, informed consent, and SC tourism are equally alarming, that compelled many to enact laws and policies to regulate SC unlike Malaysia. [5-9]. In Malaysia, while SC technology is progressing as presented in Fig 1, it is overlooked by the Guideline for Stem Cell Research and Therapy (2009) [10]. The former Health Minister of Malaysia commented that the ministry has no intention on enacting a law on SC yet, as it is still in its infancy [11]. With that, this study aims to explore the ethical and legal concerns of the Malaysian SC technology in pursuit of scientific excellence. It is a significant study because while it reveals the ethical and legal issues concerning Malaysian SC technology, it urges the authority to value regulation as a primary goal to ensure order and transparency for all stakeholders.

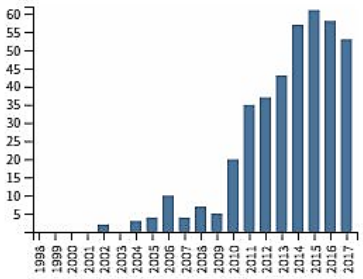

Fig 1: Malaysian Stem Cell Publication in Web of Science (WoS) (1998 – 2017)

2.0 Method

This study employed qualitative methodology that is proven effective in answering a number of research questions in fulfillment of the research objective [12]. The in-depth interview (IDI) of the Malaysian SC policymakers whom are members of the National Stem Cell Research and Therapy (NSCERT) sub-committee and the comprehensive review of significant literatures gathered from Google and Web of Science (WoS), including government documents retrieved from official portal of the Ministry of Health (MOH) and some of its subsidiaries such as the Medical Development Division, Medical Practice Division, and the National Pharmaceutical Regulatory Agency (NPRA) not only answered the research questions, but revealed many issues within the regulation of SC technology in Malaysia.

3.0 Results & Discussion

The SC policymakers verified that currently SC technology in Malaysia remains unregulated. The SC guideline is considered as recommended practice and does not carry legal mandate nor addresses the issue of exploitation and accountability. While, the increasing SC clinical trials initially pushed for its formulation in 2006, the revision in 2009 remained as the last effort directly involving SC until the recent the effort by NPRA [13-14]. According to the guideline, there are inconsistencies between the public and private sector. While, SC research and therapy in the public sector require review and approval of their institutional review board (IRB), institutional ethics committee (IEC), and the NSCERT sub-committee, the private sector deals with NSCERT directly [10]. Apart from the guideline, the government circulars carry legal mandate that the public servants are compelled to follow, whereas the private sector is required to conform to the Private Healthcare Facilities and Services (PHFS) Act 1998. Since SC research involves the review and approval of NSCERT (and Medical Research Ethics Committee (MREC) in some instances) and its clinical trials involve human subjects, these therapies are required to be registered within the National Medical Research Registry NMRR [15].

3.1. The Ethical Misconducts

However, a search through the NMRR database would leave many puzzled as some private healthcare providers (PHP) have been offering SC therapies since 2012, but did not register their clinical trials until 2017, and those within aesthetic medicine are offering SC based treatments but have not submitted them for NSCERT review or approval [15]. While aesthetic medicine has its own aesthetic guideline, it does not address SC nor carry legal mandate similar to SC guideline leaving room for exploitation. The unclear oversight in these areas combined with the nation's medical tourism efforts will continue to foster SC tourism and aesthetic medicine. In 2008, a foreign SC entity signed a memorandum of understanding (MoU) with the Pahang Technology Resources (PTR), a state-owned company to lease land to breed rabbits for SC extraction. Despite making into local news, MOH was not consulted [16]. The entity did not follow the procedure nor entertain the request for sample testing by MOH, which eventually led them to seek business elsewhere.

The issue of false advertising by some PHP exploit the vulnerability of the public who believe the information to be valid and true. While advertising is not addressed in the SC guideline, it is within the PHFS Act 1998 [17]. The Medical Practice Division handles the monitoring and regulation of private sector which includes licensing and registration of PHP and reviewing advertisements [18]. Although, it applies to all types of healthcare, the facilities that offer SC therapies are required to seek NSCERT sub-committee's approval of their advertisement. However, a search in Google proves otherwise, as many have successfully advertised their procedures without approval, as verified by the NSCERT sub-committee. Besides the unproven SC therapy, the wide range of SC based wellness products imported from countries like South Korea, Japan, and China are also extensively advertised in company websites, social media, and magazines, but majority of them are not licensed or approved based on a product search through the NPRA Quest 3+ [19].

3.2. Towards Scientific Responsibility

The SC guideline help guide scientists regarding acceptable and questionable conducts in research and therapy. Although, some scientists believe it is pointless and ineffective, considering the complex nature of SC research, some claim adopting it is laborious and diverts attention from actual scientific pursuit [20]. In the absence of clear regulation, the ethical misconducts are explicitly prevalent in private sector. Although NPRA have released the 'Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia 2015', it is currently on the basis of voluntary and expected to take full effect by 2021 [21]. According to this guideline, the cell and gene therapy products will be initially classified by NPRA and required to the meet the subsequent criteria and regulatory pathway (based on their classification) as presented in the guideline. This new guideline, unlike SC and aesthetic medicine, is linked to the Sales of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984 bestowing it with legal statute. While self-regulation is key in recognizing errors and misconducts involving scientific freedom, integrity, collegial work-relationship, it is only achievable with

federal oversight and regulation accomplished with laws and policies that offer clarity, consistency, and address all stakeholders for an effective oversight [21]. The most important thing is striking a balance. A regulatory policy would be ideal to not only bestow the mandate the guideline lacks but address the issue of accountability to foster an ethical scientific pursuit. Currently the CGTP guideline will be on voluntary basis and it is unknown how it will affect ethical conduct of SC technology by 2021.

4.0 Conclusion

While the red-tape of bureaucracy has delayed the regulatory progress, the absence of law and policy has resulted in exploitation and misconduct. Although, there is a possibility of concurrent undertaking (licencing and approvals), no review takes years, therefore ruling it out. While PHP are motivated by profit-gain, their violation could also be due to unclear regulation which SC policymakers should address while they execute a trial regulation based on CGTP guideline in the next four years, as the saying goes, 'better late than never'.

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