UNIVERSITI TEKNOLOGI MARA

THE BENEFITS AND HARMS OF ROBOTIC-ASSISTED SURGERY IN MALAYSIA: AN ETHICO-LEGAL ANALYSIS

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ABSTRACT

Robotic-assisted surgery is the latest surgical approach adopted in many surgical disciplines. This medical intervention is still considered as a new technology in Malaysia healthcare industry, judging from the use and availability of this technology which are privileged to certain hospitals and still are not very popular. However, since other surgical approaches such as minimally invasive laparoscopic and conventional open method are still available in the market, there is a need for robotic-assisted surgical approach to be evaluated not just from a clinical point of view, but as well as ethical and legal perspectives. This is to ensure that the both known and unknown harms and risks are being identified and encountered beforehand. There are many legal implications are foreseeing to occur as this surgical approach is a new technology. Hence, this study will discuss some of the important legal implications of robotic-assisted surgery and compare the regulation and legislation of robotic-assisted surgery available in Malaysia with another country such as the UK. At the end of the study, we concluded that the robotic-assisted surgery offers maximum benefit in certain types of surgery such as prostatectomy and TORS. Although the procedure is safe with many precautionary measures in place, it is recommended for the training and credentialing process to be extended and revised based on local needs. For community to be able to enjoy equal access to the robotic-assisted surgery, more studies need to be done to evaluate cost-effectiveness of the procedure compared with other surgical modalities. Also, it is recommended that separate and more comprehensive consent form is established for the surgical procedure involving new technology. The issue is liability is unclear when it comes to robotic-assisted surgery. By establishing black box system and proper documentation, it will ease every party when litigation takes place. In term of regulation, both Malaysia and the UK have almost similar structure of legislative framework. However, there are lacking provision to restrict inexperienced surgeon from using the technology. Improvisation of the current law is needed to allow this nation to be ready to face the legal challenges that comes together with this technology.

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CHAPTER ONE
INTRODUCTION

1.1 Research Background

Robotic-assisted surgery refers to technological development to aid surgical procedures by using robotic systems. In the meantime, Shreuder defined robotic surgery as a surgical procedure where the surgical team is locating at any distance from the patient and operating theatre (OT) (Schreuder and Verheijen 2009). The development of the robotic system in medicine is the part of an effort in shifting the surgical field into the industrial revolution that is moving very aggressive globally, known as artificial intelligence (AI). In this so-called Revolution 4.0, aims to replace work that usually performed by a human to robot or machine which targeted to produce a better outcome and reduce human involvement (Russell, et al. 2003)

The usage of robot started when General Motors developed a robot called the *Unimate*, which helped to minimise the risks of injuries to their workers. Due to the reported success in the heavy industries, the application of robot began to emerge and adopted into the healthcare industry. Earlier, robots were created to help some basic tasks in a hospital. As reported by Siqueira-Batista, hospitals in California of the United States of America (USA) uses the robotic system to transport drugs, food, utensils and other medical equipment. This task reassignment has been useful to minimise the need for workforce, thus allows professionals to focus on the other more critical tasks. McKesson Company has innovated this technology since then to where it is later capable of preparing drugs for enteral and parenteral usage (Siqueira-Batista, et al. 2016).

Robots are already used in the surgical field for many years now. The forerunner of *nueormate* is one of the first robots to be used in the medical industry, which was approved by the Food and Drug Administration (FDA) in 1999. This device helps to perform stereotactic brain biopsy accurately at 0.5mm. The application of robot in surgical procedures has been widely used since then as many robots were introduced to assist surgeons such as *Robodoc* for hip prosthesis replacement operation, *AC Robot* for knee operations, *RX-130* for surgery at the temporal region and many more to be