

TECHNOLOGICAL DIVERSITY MANAGEMENT OF MEDICAL DEVICE ENTERPRISES

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ABSTRACT

Background: Technological diversity management in the manufacturing of advanced medical devices is essential. The manufacturing industries of medical devices should act in accordance with the technical guidelines and regulations in order to ensure best practices with the use of devices in hospitals

Aim: To explore safety hazards, cost implications, and social and ethical standards to be considered during the manufacturing of advanced medical devices

Subject and Methods: A qualitative descriptive study was used. There was no targeted sample in the current study whereby secondary data were used to explore the research topic. Secondary sources were obtained from databases including EBSCOHOST, PubMed, ProQuest, Science Direct, and Google Scholar. Peer-reviewed articles, journals, books, conference proceedings, and other web publications were used to gather relevant data.

Results: The current study indicated that the technological diversity management of advanced medical devices is associated with safety hazards like security threats, integrity problems, and medical errors. The study also showed that high cost of standardizations, supply, and purchase of advanced medical devices is a huge burden faced by the manufacturers and users. The study showed that the regulation of the medical devices, certification, and post-market surveillance are essential social and ethical considerations during the manufacturing process of the new medical devices.

Conclusion: The current study explored the technological diversity of advanced medical devices. It is evident in the current study that technology diversity of medical devices is associated with safety hazards and cost implications. The study disclosed that taking into account social and ethical issues aid in manufacturing safe and high quality medical devices.

Keywords: *Advanced medical devices, Technology diversity management, Social and ethical issues, Safety hazards*

INTRODUCTION

Technological diversity plays a significant role in the innovation of medical devices. Successful innovation of medical devices in the medical device firms is an important element for the maintenance of healthcare strategy (Shimanuki & Saiki, 2012). The healthcare threats that medical devices may pose to human health and safety makes the application of technological diversity a necessity. The adoption of operation management assures the compliance with health safety and quality standards throughout the manufacturing process of medical devices (Gadotti Martins, Pinheiro de Lima & Gouvea da Costa, 2015). The modern healthcare practices thus rely on the use of advanced medical devices in order to ensure the effective treatment of acute health problems and in the management of chronic diseases (Kirisits & Redekop,

2013).

Technological diversity management in medical device industries is aimed at improving health care. Technological innovation of the devices greatly promotes the life expectancy as well as the quality of life for both patients and the healthcare providers. This improved healthcare is achieved through the development of advanced medical devices that are effective in the diagnosis and treatment of health conditions (Billaux *et al.* 2016). With technological diversity in the manufacturing of medical devices, most implantable medical products have been improved. The manufacturers focus on adopting innovative technological solutions in the medical device industry that assist in responding to the complex challenges that arise during the provision of health care practices (Joung, 2013). The diversity of medical devices and the

barriers that exist in the manufacturing industries lead to complex issues in the market of medical devices.

Therefore, the manufacturers should demonstrate thoughtful knowledge of management policies to enhance quality and safety of medical devices (El-Haik & Mekki, 2011). Additionally, the majority of medical device manufacturers should ensure quality management of the medical devices and their conformity assessments to assure reduced production of hazardous products in the manufacturing industry (El-Haik & Mekki, 2011). El-Haik and Mekki (2011) found that the regulation and management of advanced medical devices is achieved by ensuring that the personnel who use to the devices have appropriate education, training, and experience with the advanced medical devices. Thus, the manufacturing sectors should develop and monitor the procedures on the use of devices to ensure that the medical requirements of quality and safe health care are achieved.

Statement of the Problem

Technology has been the driving force in the healthcare. Technological developments from antibiotics and anesthetics to the use of advanced medical devices like radiotherapy and imaging devices has dramatically changed the healthcare practices (Thimbleby, 2013). While the adoption of advanced medical technologies such as the use of new drugs and treatments and the adoption of new devices to support healthcare practices, human factors remain the key limitations of breakthrough to achieving quality and safe health care (Thimbleby, 2013). The innovation in healthcare organizations in relation to health technology, particularly in the current clinical practices, has resulted in improved clinical innovativeness and advanced therapeutic practices (Ciani *et al.*, 2016). Due to the innovation and the rapid advancement of health technologies, medical devices are among the fastest advancements in the manufacturing industries and in the global market. As a consequence, it is critically essential that continuous assessment of safety and performance of medical devices be conducted for unforeseen problems (Wong & Kaiyu, 2013). This assessment is essential during the post-market surveillance which unveils the possible failures or incidents with the use of medical devices. The post-market surveillance allows the manufacturers to adapt the regulatory requirements for the approval of medical devices (Altenstetter, 2011). Additionally, the surveillance allows the manufacturers and users of medical devices to balance medical

vigilance and the medical devices in the market. This assists in ensuring effective maintenance and management of professional rights to clinical practices and maintenance of property rights to healthcare facilities (Altenstetter, 2011).

Wong and Kaiyu (2013) identified that good and functioning medical devices are developed when there is effective management of manufacturing processes. However, the lack of management can contribute to inconsistency in the quality of medical products. Despite that medical devices are required to satisfy the clinical demands like safety and performance, the regulatory scrutiny of the devices is low and some medical products may be exempted (Wong & Kaiyu, 2013). The manufacturing industries of medical devices in various countries lack access to high quality medical devices due to little regulatory controls that are suitable for particular epidemiological needs. Similarly, most of the medical device manufacturers do not take into account the ethical aspects of technological diversity in the development of medical devices. This is because the regulatory policies and guidelines adopted appear to be inadequate (Shimanuki & Saiki, 2012). Therefore, there is need to assess the technological diversity during the manufacturing of advanced medical devices. The necessity to explore technological diversity management of advanced medical devices forms the basis of this paper. The study seeks to explain the technological diversity management of medical devices with a focus on bioethics during the manufacturing processes of advanced medical products.

Significance of the Study

The current study explores the technological diversity with the use of advanced medical devices. The study examines technological management of these devices which forms of the basis for increasing the body of knowledge of manufacturers and users of advanced medical devices reflected in the clinical practices. The results of this study significantly contribute to existing knowledge of delivering quality and safe health care to patients in the hospitals. Additionally, the study increases the baseline data for literature review related to the impact of technological diversity on quality of life and success rate of clinical practices. The results of the study will form the basis for manufacturers to take into account the bioethics associated with the establishment of advanced medical technologies for improved quality of care delivered to patients. Taking

into considerations the bioethics of medical device manufacturing will allow health care professionals and hospitals to mediate for all patients in ensuring cost effectiveness of diagnosing, treating, and management of health care conditions with the use of advanced medical devices. The study has significant benefits to the manufacturers of medical devices since it will provide appropriate information on technology management of medical systems in producing quality advanced devices in the global market. The study presents insights that will enable manufacturers to comply with the bioethics and the emerging ethical aspects during the manufacturing process of advanced medical devices.

Purpose of the Study

The study is aimed at exploring the technological diversity and management of medical devices activities. The study specifically investigates the management practices in the manufacturing processes of technological advanced medical devices. The study focuses on exploring the manufacturers' approach to bioethics while developing advanced medical devices and their management practices to ensure high quality advanced medical devices in the global market.

The main objectives of the study include:

1. To examine safety hazards associated with the manufacturing and use of technologically medical devices
2. To investigate the cost implications of new advanced medical devices in hospitals and medical device industry.
3. To examine social and ethical standards to be considered during the manufacturing of advanced medical devices

LITERATURE REVIEW

Medical innovation assists in exploring the development of advanced medical technologies. The innovative medical technology ensures improved quality of life for the patients (World Health Organization, 2010). The development of medical devices requires knowledge acquisition for successful management. The adoption of core technologies for medical devices ensures the success of the products in the market (Shimanuki & Saiki, 2012).

Diversity in the development of medical devices is a

requisite for health care innovations. Diversity is important for the accomplishment of varied enterprises during the development of innovative health technology (Shimanuki & Saiki, 2012). In addition, the manufacturing of advanced devices is essential in the pursuit of internalization of research and development. The achievement of functional diversity and business activities are the main components of diversification which are needed to achieve health care innovations (Koch, 2011). The design and development of medical devices should be effective in addressing the desired set of medical tasks (Hagedorn, Krishnamurty & Grosse, 2016). This action needs to the engagement of stakeholders to examine the needs and the capabilities of users and the required methods to assess the development decisions from users' perspectives (Hagedorn *et al.*, 2016).

Safety Hazards of Technological Medical Devices

According to El-Haik and Mekki (2011), the medical device manufacturers are needed to have adequate knowledge and skills regarding the regulatory and quality management of medical devices. Manufacturers are required to possess such knowledge and skills to ensure the production of safe and high quality medical devices. Additionally, El-Haik and Mekki (2011) found that the quality management of medical devices is set up by manufacturers to oversee the delivery of high quality and the application of advanced medical devices that meet healthcare needs. The United States of Food and Drug Administration (FDA) is one of the well-known agencies that provide regulations of food, drug, medical devices, and even the radiation-emitting medical products. These agencies aid in safe guarding the consumer of medical products through the enforcement of federal laws and policies that ensure all medical products are well labeled and provide truthful information regarding the use of the products. FDA has a key role of making sure all the technological diversity of medical devices have correct information in order to be adopted and used safely and effectively in healthcare organizations. This indicates the roles of FDA as the regulatory agency for all kinds of medical devices.

Despite the enforcement of regulatory policies on the use of medical devices, there are also complexities with the safety of using medical devices on human bodies. Due to the evolvement of technology in the manufacturing of medical devices, the threats towards the safety of medical device users such as patients and

service providers have been experienced (Burns, Johnson, & Honeyman, 2016). The modern medical devices are manufactured using electrical and mechanical components which may have safety threats to the human body. The manufacturing companies of advanced medical devices use software that poses security threats to health. These devices are highly prone to cyber-attacks that may affect the safety of people using them. The ECRI Institute (2015) showed that the most frequent safety hazards of technological medical devices include poor patient handling of the medical devices, integrity problems, alarm hazards due to the lack of sufficient configuration practices, and dose creep from radiations that contribute to poor administration of medical drugs (ECRI Institute, 2015).

Besides, the software-driven medical devices are released to the market with insufficient information or high quality data to assist the consumers in using the advanced medical devices. The insufficient high quality data thus contributes to uncertainties in making decisions when using technological advanced medical devices on human bodies. Also, the users of medical devices may experience uncertainty due to the implementation of devices that are ineffective and the lack of safety policies (Billaux *et al.*, 2016). Some other patients who use such medical devices may worsen their health conditions following the miss administration of medical devices. The safety threats posed by the technological advancement in medical devices have resulted in the establishment of international regulatory laws and standards which are applicable to each of the devices (Billaux *et al.*, 2016). This establishment ensures that all kinds of medical devices undergo constant updates and revisions to assure potential management and maintenance of safety concerns of the advanced medical devices to the users' bodies (Billaux *et al.*, 2016).

Cost Implications for Technological Diversity Management of Medical Devices

The development and management of technological advanced medical devices is a challenging task to the users and manufacturers of medical devices. Only limited manufacturers are allowed to produce advanced medical devices. Consequently, the purchase price, management and maintenance, and the applications of the medical devices are high and pose a burden to various users especially patients (Simoen, 2009). In addition, the process of ensuring that the

advanced medical devices are safe and provide high-quality services to the users is costly and various developing countries experience a huge burden for the maintenance and management of these devices (Dybczak & Przywara, 2010). The increased price and the high cost of maintaining and managing the technologically advanced medical devices increase the expenditure incurred by manufacturers and users of these devices. The health expenditures with medical devices are associated with the need to ensure quality of life among patients and improved healthcare, constant technological innovation, and increased income growth (Simoen, 2009). Such expenditure leads to increased health insurance coverage for the medical devices. Additionally, the demand for technological advanced medical devices in the global market escalate the prices required to achieve effective devices for care, diagnosis, and monitoring of patient health (Simoen, 2009). Also, the assessment processes by the regulatory agencies that govern the pricing as well as the reimbursement of technologically advanced technologies are lacking. Similarly, the collaboration between the hospitals, service providers, and the manufacturing bodies is a challenge. This requires a huge pricing in order to ensure the delivery of cost-effective medical devices to the users in the market (Simoen, 2009).

Based on the cost implication issues associated with the use of technological advanced medical devices, the regulatory firms have focused on providing appropriate guidelines to ensure effective management or maintenance of a low cost medical device. This regulation process is linked with reduced cost incurred by medical device manufacturers and other users of the devices (Kreis, Panteli, & Busse, 2014). However, patients may not afford the treatment with the advanced medical devices due to higher costs of treating some chronic health conditions. The higher costs of medical devices that are experienced by the consumers, healthcare providers, and the healthcare organizations is associated with improved maintenance care of the devices (Kreis, Panteli & Busse, 2014).

Social and Ethical Issues in the Manufacturing of Technologically Advanced Medical Devices

Integrating advanced medical devices in the medicine field significantly promotes the health standards across the globe. Despite the effective integration of the technology in the medical field, the ethical and social concerns in the development of devices is required

which manufacturers should comply with (Wahlster *et al.*, 2015). These ethical and social considerations in the manufacturing of medical devices serve as the norms of conduct that help in differentiating the acceptable and unacceptable behaviors (Wahlster *et al.*, 2015).

The basic ethical and social issues that the manufactures take into the consideration while developing advanced medical devices include registration and licensing processes. The medical devices should be approved by the FDA regulatory body before being used for any healthcare operations (Polisena, Gagliardi, & Clifford, 2015). During the development of medical devices, the manufacturers make sure that they meet and exceed the expected standards required for the safety and effective performances of the medical devices.

Reporting any severe incidences with the use of advanced medical devices is another ethical consideration adhered to by the manufacturers. Kreiwall (2008) found that the manufacturers report any death and serious issues to the FDA base on the health condition of the users. Serious health issues with the use of devices are reported to the regulatory bodies based on the opinions and thoughts of healthcare professionals and the evidence of health incidents. The manufacturers of advanced medical devices strive to ensure proper packaging and labeling of the instructions on the devices (Kreiwall, 2008). This helps in ensuring the safety of the devices and proper utilization of the medical devices. In such cases, the manufacturers need specialized training on the use of the medical devices to ensure effective operations and safety of devices in the market (Kreiwall, 2008). Post-market surveillance is also a basic social and ethical consideration in the manufacturing of technological diversity of medical devices. The post-market surveillance is achieved through the assessment of the complaints made by the customers and the incidents of serious issues associated with the use of medical devices. The manufacturers analyze the complaints and establish the health procedures of reviewing and maintaining the complaint files which can be used to the document of compliance evidence of regulatory policies (Feijter *et al.*, 2012). Analyzing and reporting any complaints with regards to the use of advanced medical devices assists in resolving the shortcomings that appear in relation to the performance of the devices. This also helps in improving the effectiveness of producing and in enhancing the efficacy of the medical devices (Feijter *et al.*, 2012).

METHODOLOGY

A qualitative descriptive research design was applied in the study to explore the technological diversity management of medical device manufacturing. In descriptive research design, the main points with respect to the topic of the research study are summarized and used in the development of grounded theories (Colorafi & Evans, 2016). As such, the qualitative descriptive design was applicable in the study because it helped in exploring the technological diversity management of medical devices and summarizing the main points from the existing literature in order to develop new theories. When using descriptive research design, the study problem is investigated in its natural setting and in-depth descriptions are provided but the researcher is unable to manipulate the research problem (Colorafi & Evans, 2016). As a result, descriptive research design was the suitable for the study since it provided an all-inclusive abstract of the statement of the problem through a natural perspective. The design was found auditable because the study did not necessarily require the participation of human subjects in order to develop the grounded theories from participants' perspectives.

Sample

Sampling in a qualitative research is the selection of a group of people from a particular population. The sample of a study involves people with enough skills and experience in the field of research (Cleary, Horsfall, & Hayter, 2014). However, the study sample was not necessary in this study because secondary data was used to address the research objectives. The secondary data enables one to respond to the research problem with the use of available literature or primary data that have been conducted by other researchers. The study used existing literature that addresses the research topic.

Data Collection Tools

To accomplish the research purpose and objectives of the study, secondary sources were used. Secondary sources involve application of available data in the literature to address the research topic or study questions (Johnston, 2017). The secondary data are obtained from the existing empirical research in order to get adequate insights on what is already known about the research topic. This gives extensive explanations of the research topic. The most applicable sources of acquiring secondary data include books, journals,

conference proceedings, magazines, and even Internet sources (SaniCln, 2013). In this study, the secondary data were obtained from Internet search engines including EBSCOHOST, PubMed, ProQuest, Science Direct and Google Scholar. The sources included peer-reviewed journals, books, and other academic scholars. Previous and current researches were used to get deeper insights about the relevant literature of the research problem. The application of these data collection tools helped in offering scholarly evidences on the manufacturing of technologically diverse medical devices.

PROCEDURES

Relevant materials were retrieved from the databases. Key terms were developed to ensure appropriate articles were obtained. The key phrases included “technological diversity management and manufacture of advanced medical devices”, “technological diversity and management of advanced medical devices for the manufacturers”, and “ethical and social concerns of advanced medical devices during manufacturing enterprises”. Articles that were deemed suitable were reviewed by reading their abstracts and performing full-texts reading to ensure that they provided adequate data on the research topic. The articles that were found eligible for the study were screened for final review. Those articles that successfully met the criteria were used to qualitatively analyze the research problem.

Analysis of Data

The obtained data were analyzed using descriptive analysis method. The descriptive method of data analysis involves summarizing the key points from the existing articles or secondary materials in order to get better and clear meanings of the research topic. The descriptive analysis approach analyzes the documentary data retrieved from the secondary sources (Neale, 2016). As such, qualitative data obtained from the secondary or existing sources were analyzed using descriptive analytical approach where each of the appropriate articles was reviewed. A summary of the main points that were consistent with the research problem was made. This helped in providing exhaustive and detailed information of the research aims and objectives.

RESULTS

The purpose of the study was to examine technological diversity with the use of advanced medical devices. The

study specifically aimed at exploring the safety hazards associated with the technologically advanced medical devices. Also, the aims of the project were to examine cost implications and the social and ethical issues with the development and use of technologically advanced medical devices. The purpose and objectives of the study were achieved by reviewing the existing literature in relation to the research topic. Secondary data were explored throughout the study. Articles were retrieved from databases including EBSCOHOST, ProQuest, and Science Direct.

Presentation of Findings

Articles were reviewed and analyzed with respect to the topic of the research. Two articles (Bolka, 2014; Holtzman, 2012) clearly described the security hazards associated with the manufacturing of technologically advanced medical devices. The findings showed that the regulatory task and competition in the global market are the main challenges or safety hazards of the manufacturing devices. The regulatory and global competition challenges affect the delivery of high quality and safe medical devices in the market. Besides, the study established that the manufacturing companies lack sufficient regulatory guidelines and the policies on the procedure for the approval of advanced medical devices. As a result, the delays and complications with the use of the devices increase (Bolka, 2014). The study also found that despite the support regarding the use of advanced medical devices by patients, caregivers, and healthcare professionals, they may also have limited medical and technical expertise as well as experiences with the use of the devices. Two articles (Bitterman, 2011; Hilbers, de Vries & Geertsma, 2013) showed that the healthcare providers such as home care professionals have limited opportunity to acquire sufficient skills with the use of all medical devices that they come across during their daily work operations. As a result, the professionals are more likely to cause errors while using complex devices and have little or no knowledge in dealing with unexpected health situations. Safety hazards of advanced medical devices are also associated with poor storage, maintenance, and calibration. The study revealed that technical defects with the manufacture of medical devices lead to clinical problems that affect the quality of patient life. The study by Williams and Woodward (2015) also disclosed cyber security vulnerability as the safety hazard to the technologically advanced medical devices. The integration of advanced medical devices is complex

and the users of the devices experience challenges in the management and protection. The study revealed that with lack of sufficient protection, the advanced medical devices are highly vulnerable to malicious damages as well as security breaches that affect the safety of the devices.

The study also explored cost implications with technological diversity management of medical devices. The studies by Kumar (2011) and Ventola (2008) showed that the healthcare costs for advanced medical devices are high. Hospitals and manufacturers of medical devices encounter high costs of standardization. Ventola (2008) found that standardizing medical devices result in higher costs. As such, hospitals face increased costs of supply and in purchasing standardized devices in order to acquire safe devices. A study by Sorenson, Drummond, and Bhuiyan Khan (2013) indicated that the new medical technology has resulted in burgeoning healthcare expenditures. The technological advancement contributes to consumer demand for costly health services and higher demand for insurance. The development costs of the medical devices lead to higher prices because of the need for regional procurement and management practices Sorenson, Drummond and Bhuiyan Khan (2013)

The study is also investigated the social and ethical issues with technological diversity of advanced medical devices. A study by Ross *et al.*, (2010) found that the most essential social and ethical factor in the manufacturing and use of advanced medical technology is regulation. The manufacturers of the devices should take into consideration the FDA regulations through classification and performing post-market surveillance of the devices to assure the safety and provision of high quality products in the market. Also, Barakat, Sunny, and Hasan (2014) indicated that safety and welfare of human beings is an important social and ethical issue in the manufacturing and use of technologically advanced devices. The study showed that the designers or manufacturers of medical devices should balance the safety and the demands or the devices before releasing the users in the global market. A study by Lehoux *et al.*, (2014) showed that the ability for designers to take into consideration the social and ethical aspects like the demands and the safety and risks of the medical technology lead to improved health innovations with the use of new advanced medical technology. Certification is also an ethical concern in the manufacturing of technological diversity of medical

devices. A study by Zarmani, Ramli and Shaikh MohdSalleh, (2014) showed that the manufacturers of new medical devices should comply with the quality standards like the ISO certification in order to find entry of their products to the global market. The article showed that producing certified medical products in the medical device industry assures the moral obligations of the manufacturers and promote the legitimate relationship between the users and manufacturers of the devices (Zarmani, Ramli and Shaikh MohdSalleh, 2014)).

DISCUSSIONS

Regarding the technological diversity management in the manufacturing of medical devices, the current study showed that the security hazards during the manufacturing of advanced medical devices is the main concern. The study found that the lack of regulatory compliance the security standards in the competitive market of new medical technology affects the provision of high quality and safe medical devices to the users. The findings of the current study is in accordance with the information presented by Burns, Johnson, & Honeyman (2016) that showed that the safety hazards with the manufacturing of medical devices involve security threats. The threats with the use of medical devices are associated with the use of electrical and mechanical components that pose safety threats to the human bodies. Also, the results of the current study were in consistent with the information presented by ECRI Institute (2015) that showed that cyber threats with regard to the manufacturing of medical devices are associated with integrity problems and insufficient configuration practices that may contribute to errors with the use of medical devices.

The current study also found that the lack of enough skills with the use of technologically advanced medical devices leads to medical errors, especially with the use of complex devices. The study disclosed that healthcare professionals with limited skills on the use of complex devices found challenges when delivering care using the advanced devices. The current study also disclosed that poor calibration, improper storage and poor maintenance also lead to safety hazards of the devices. These results align with the findings of the study by Billaux *et al.* (2016) that revealed that the lack of sufficient skills among healthcare professionals may contribute to misadministration of medical devices. The lack of sufficient skills worsens the health situation and may lead to poor maintenance of medical devices.

Cost implications in relation to the manufacture and use of medical devices were also investigated. The current research found that the healthcare costs for the medical devices are high. The study disclosed that the cost of standardization and the supply and purchasing of the standardized advanced medical devices is high. Therefore, healthcare organizations and the manufacturers experience are high expenditures that affect the delivery of quality services and development of improved medical devices. These results are consistent with the findings by Simoen (2009) that indicated that the cost of buying the medical devices and their maintenance is high which provides a huge burden to the users and the manufacturers. The results also aligned with the information by Dybczak and Przywara (2010) that manufacturers face huge costs in the development of safe and medical devices. Also, it was found that the maintenance and management of the devices by the users is costly.

The social and ethical considerations were also examined in the current study. It was found that the regulation of the medical advances was the main consideration while manufacturing and using the devices. The study established that seeking FDA regulations and conducting post-market surveillance are the ethical considerations with respect to the manufacturing of technological diversity of advanced medical devices. The results are consistent with the findings by Polisen, Gagliardi & Clifford (2015) that indicated that seeking FDA regulations through registration and licensing of medical devices enable the manufacturers to produce safe devices to the market. Developing regulatory policies assist in proper labeling and packaging of the medical devices and this helps in assuring the use of safe and high quality products (Kreiwall, 2008). Certification was also found in the current study as a social and ethical consideration during the manufacturing of the advanced medical devices. The current research found that post-market surveillance allows the manufacturers of the medical devices to ensure the development of safe and high quality products. It assists in analyzing and reporting any complaints with the use of medical devices hence allowing the manufacturers to take into considerations the health incidences based on the feedbacks of the products already available in the market. These findings were consistent with the existing literature by Feijter *et al.* (2012) that indicated that post-market

surveillance promote the development of technological diversity of medical devices

CONCLUSIONS

The findings attained in current study led to the conclusion that technological diversity management of advanced medical devices has significant impacts to the manufacturers and users of the devices. The study concluded that the manufacturing of technologically advanced medical devices poses safety hazards like integrity and cyber security attacks that may lead to poor maintenance and management of the devices. Social and ethical considerations like the regulation of the devices, reporting complaints in relation to health incidents on the use of advanced medical devices, and performing post-market surveillance are the main social and ethical considerations in the development of the devices.

RECOMMENDATIONS

Due to insufficient skills with the use of complex medical devices by some healthcare professionals, it is recommended that proper training and education with the use of technologically medical devices be adopted across hospitals. Also, the study provides recommendations for manufacturers to comply with regulation policies and standards of medical devices to ensure the effective development of safe and high quality devices. The study recommends that the manufacturers of advanced medical devices should ensure regulation of the devices and proper certification before releasing the products to the market.

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