Factor Analysis of Implantable Medical Device Adoption for Efficient Healthcare Management in the United States

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Approval Page

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Abstract

On the heels of the COVID-19 pandemic, discussions within healthcare institutions and the public at large concerning the inefficiencies pertaining to health management in the United States have heightened. Innovative technologies for efficient health management include implantable medical devices, yet their adoption rates remain low. The purpose of this quantitative, nonexperimental correlational study was to examine whether U.S. patients' perceptions of device performance expectancy, perceived credibility, facilitating conditions, attitudes, and social influence, determine their behavioral intent to use an implant in a voluntary setting. An extended unified theory of acceptance and use of technology model constituted the theoretical research framework. A sample of 363 randomly selected Facebook IMD Support Group members residing within the United States was anonymously surveyed, after which 246 entirely completed responses were considered satisfactory for data analysis. Exploratory factor analysis was initially conducted using the Statistical Package for the Social Sciences version 28 software followed by confirmatory factor analysis in the analysis of moment structures software version 26, to ascertain the significant factors and the validity and reliability of the measurement model. The structural model was subsequently investigated using the covariance-based structural equation modeling and path analysis techniques within AMOS. Model-fit statistics of, $\chi 2/df = 1.438$, $p < .001$; CFI = .965; IFI = 0.966; RMSEA = 0.042; TLI = 0.949; NFI = 0.90; RMSR = 0.077; GFI = 0.922; PRatio = 0.696; PCFI = 0.671; PNFI = 0.623; RFI = 0.849, suggested the model was well suited to the data. The research findings suggested that perceived credibility, performance expectancy, and social influence were the significant prognosticators that positively predicted the behavioral intent to use an implantable medical device. Utilizing multiple linear regression analysis, the partial mediating effect of perceived credibility on performance expectancy was also established as positive.

These findings will assist healthcare policymakers, device manufacturers, and medical doctors take well-informed decisions which will inure to the benefit of U.S. patients. Recommended for future research is the examination of the extent to which U.S. patients' attitudes toward implantable medical device adoption is mediated by facilitating conditions.

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Chapter 1: Introduction

In the United States, inefficiency within the healthcare delivery system continues to be problematic. The inefficiency within the U.S. healthcare system has become a source of concern for healthcare institutions, the U.S. government, and the U.S. public at large (Himmelstein & Woolhandler, 2020; Ratna, 2020; Speer et al., 2020; Wu, 2020). The inefficiencies are partly derived from the United States spending more on healthcare as a share of the economy, precisely 17.7% of its gross domestic product (GDP). The 17.7% of GDP is more than twice as much as the average organization for economic cooperation and development (OECD) country, 8.7% of GDP, yet has the lowest life expectancy among the 11 member-nations (OECD, 2020). This trend reflects a relatively low life expectancy along with higher COVID-19 mortality rates and a generally weak economic outlook.

More recently, during the COVID-19 pandemic, some of the inefficiencies could be observed in the management of healthcare facilities in forms such as low physician-to-patient ratios, lapses in emergency room admission protocols, overwhelmed healthcare facilities, inefficiencies in the delivery of COVID-19 vaccines, among many other issues (Kemp et al., 2021; O'Reilly-Shah et al., 2020; Peters, 2020; Russo et al., 2020; Sassone et al., 2020). Some of these inefficiencies could have been reduced and tens of thousands of lives saved with the help of innovative healthcare technologies such as implantable medical devices (IMDs). Other technologies that could make the healthcare system more efficient include telemedicine, wearable personal Internet-of-Things (IoT) devices, and chatbotting for diagnosis based on patients' identified symptoms.

IMDs are implanted to treat and monitor various patients with diverse types of individual or multiple medical conditions such as heart disease, lung disease, and nervous system complications (Food and Drug Administration [FDA], 2017; Sasangohar et al., 2020; Wu, 2020). Further research must build on what is already known and what would benefit the patient as the end-user in terms of usability, safety, security, cost-effectiveness, and other parameters that may not be immediately evident. The low IMD adoption rates may as well be an aspect of a broad landscape consisting of factors such as the increasing complexity of medical devices, the business environment in which medical devices are developed, the innovation process, and the global medical device regulatory consortium (Banerjee et al., 2019; O'Reilly-Shah et al., 2020). Critical to public health is the long-term security of the devices, the safety of the patient, and general effectiveness of the devices (Rohrich et al., 2022). When treatment risks and outcomes are not guaranteed, leading to the reluctance of the patient to adopt the device(s), patient engagement with healthcare managers (physicians) may become necessary.

Previous research has suggested that patient engagement on the issues and decisions bothering IMD adoption were not encouraged by their physicians (Banerjee et al., 2019; De Larochellière et al., 2020). There is limited research on IMDs from a patient acceptance viewpoint. Gagliardi et al. (2017) investigated the factors constraining patient engagement in IMD discussions and decisions, and yet interviews were conducted with physicians instead of the patients. Speer et al. (2020) and Wu (2020) have suggested that everyday use of IMDs and especially when used in times of pandemics, will help to reduce congestion at hospitals, emergency rooms, reduce physician fatigue, and improve the well-being of many who use these devices for disease condition management. However, Alsuwaidi et al. (2020) and Longras et al. (2020) have cited security, cybersecurity, and privacy concerns with using these devices. Further, Yaqoob et al. (2019) stated that IMDs are vulnerable to cybersecurity attacks. Repeatedly, researchers have established that a proven method of establishing factors influencing individuals to adopt new technology such as e-learning technologies (Twum et al., 2022), mobile internet use (Jacob & Pattusamy, 2020), and college students reception of social networking tools (Alvi, 2021) is by making use of the unified theory of acceptance and use of technology (UTAUT) model. Similar instances where the UTAUT was used include, motivating information system engineers' acceptance of privacy by design (Bu et al., 2021), and the adoption of biometric technology (Chen et al., 2021).

Decision-makers and stakeholders may be interested in this research because IMD adoption at the hospital and patient levels have implications for health technology assessments. Therefore, this study explored the technological and behavioral factors influencing the IMD adoption decision, drawing inspiration from UTAUT, the theoretical model for my research. Five factors were explored to ascertain the most critical factors patients consider before adopting IMDs for efficient healthcare management.

This research study will help contribute to a better understanding of the factors of IMD adoption for more efficient healthcare management in U.S. healthcare facilities. The relationship between these factors influencing the choices patients make about the adoption of IMDs were the focus of this research. Implications for the study include recommendations to healthcare policymakers, healthcare information systems management policymakers, IMD security policymakers, and physicians. Recommendations will cater to user concerns of device effectiveness, device affordability, device regulation, and patient-physician relationship reasons, which may become the basis for physicians to tailor IMD choices to the needs of patients and improved regulations by regulators for improved IMD adoption rates, and efficient healthcare management, which will further translate to lower healthcare costs.

Medical implants or IMDs have been in existence for well over a decade; however, the market penetration rates have not been encouraging (Gagliardi et al., 2017; Kemp et al., 2021; Zhang et al., 2020). This phenomenon may be due to several factors that have not been explored. The proliferation of the IoT, social media, cloud technologies, machine learning technologies, 5G networks, etc. makes the healthcare landscape even more complex for the average U.S. patient as well as the entire healthcare fraternity (Sasangohar et al., 2020; Zhang et al., 2020). Distributed systems and supersonic-speed internet connections coupled with agile software application development have led to innovative interconnections of two or more implantable devices, rendering the security of the devices a cybersecurity concern for patients and the entire healthcare continuum.

The results of this study are helpful to IMD manufacturers, device regulators, and physicians when presenting to patients the necessity of an IMD. In addition, other stakeholders such as the FDA and other healthcare decision-makers will be interested in this research because IMD adoption at both the hospital and patient levels, apart from helping to save lives in emergencies, have implications for health technology assessments. With the knowledge discovered after the analysis of results, the lack of theoretical knowledge of the important IMD adoption factors will be resolved and will lead to well-informed decision-making at the various stakeholder levels. Consequently, higher IMD penetration rates may be observed, leading to positive and more efficient healthcare outcomes, which will subsequently translate to the improvement of the entire U.S. economy.

Statement of the Problem

The problem addressed in this study is that, while IMDs are primarily accessible, well over 60% of U.S. patients who could have benefitted from IMD usage are not interested in taking advantage of this life-saving technology for varied reasons (Banerjee et al., 2019; Longras et al., 2020). The causes influencing the behavioral intention to use an IMD may include patients' attitudes, social influence, facilitating conditions, perceived credibility, and performance expectancy (Loughlin et al., 2021). Zhang et al. (2020) identified that 8% to 10% of the population in the United States and 5% to 6% of people in industrialized countries have experienced an IMD for rebuilding body functions, achieving a better quality of life, or for reducing mortality rates. The above statistics suggest that IMD penetration rates are low, and further research into patient IMD adoption factors is paramount to higher usage rates (De Larochellière et al., 2020), leading to reduced fatalities in emergencies improved life expectancy, among other advantages.

The salient factors influencing IMD adoption intent are not yet known because there is a lack of knowledge of the important IMD adoption factors amongst the relevant IMD stakeholders, and the relationships between the influencing factors and the IMD adoption decision have not yet been established in the literature (Alsuwaidi et al., 2020; Maresova et al., 2020). This situation has led to device regulators, physicians, healthcare managers, and cybersecurity experts having a limited understanding of the critical factors leading to the IMD adoption decision (Easttom & Mei, 2019; Yaqoob et al., 2019). Without an improved understanding of the important factors that influence a patient's IMD adoption intent, the various stakeholders will not be able to make well-informed decisions to help improve patients' well-being and save lives in critical conditions leading to a more efficient healthcare system.

Purpose of the Study

The purpose of this quantitative, correlational study was to investigate the relationships between the key factors that may influence the U.S. patient's behavioral intent (BI) to use an

IMD. United States patients' perceptions on the key influencing factors for IMD adoption as well as the extent of the relationship between the independent variables of social influence (SI), attitude (Att), facilitating conditions (FC), perceived credibility (PC), and performance expectancy (PE), and the dependent variable of U.S. patients' behavioral intent (BI) to use an IMD was explored. This study also aimed to evaluate the extent to which the predictions of PE on BI to use an IMD will be mediated by the PC variable. The study will add to stakeholders' understanding of why patients adopt IMDs, such that improved systems for designing and implementing IMD technology can be developed sustainably to increase the prospect of IMD user acceptance. The investigation's framework made use of Yeow et al.'s (2013) extension of the UTAUT model introduced by Venkatesh et al. (2003), which includes PC, PE, FC, and SI as determinants, and expand the model by including Att as an additional determinant variable.

The research instrument (see Appendix A) items was adapted from the instruments developed by Morosan (2016), Kohnke et al. (2014), and Yeow et al. (2013). Survey distribution was via Qualtrics. Sample recruitment was conducted by group moderators posting survey recruitment flyers with survey links in the relevant Facebook support groups. The population will consist of patients over 18 years of age residing within the United States suffering from a disease condition for which a physician would recommend an IMD. Relevant Facebook support group members constituted a sample size of 246 respondents. Structural equation modeling (SEM) within the Statistical Package for the Social Sciences (SPSS) Analysis of Moment Structures (AMOS) version 26 was used in factor analyses and SEM.

Introduction to Theoretical Framework

The theoretical framework for my study is the UTAUT, introduced by Venkatesh et al. (2003). Behavioral intent has been used as a reliable determinant of technology use

(Attuquayefio & Addo, 2014; Thomas et al., 2020). Developed by Venkatesh et al. (2003), UTAUT is a well-accepted framework for technology adoption theory and hence suitable to this study and the study's construct of BI to use an IMD. This new unified theory indicates the behavioral intention to accept and use modern technology (Sundaravej, n.d.; Venkatesh et al., 2003).

The four critical constructs on which UTAUT was built consist of: (a) performance expectancy, (b) effort expectancy, (c) social influence, and (d) facilitating condition. These four unique constructs of the UTAUT have been used to understand the acceptance and the use of different technology types in varied environments. This model's usage has proven to have both satisfactory validity and reliability (Attuquayefio & Addo, 2014; Lancelot Miltgen et al., 2013). With the incorporation of the eight concepts, UTAUT offers an improved understanding of technology adoption by users. The UTAUT model has been applied in several areas to investigate issues concerning technology adoption in e-shopping (Hino, 2015), telemedicine (Kohnke et al., 2014), and the national smartcard use in Malaysia (Yeow et al., 2013). The four UTAUT constructs form part of the independent variables for this study.

Gender, age, experience with devices, and voluntariness are moderation components that interact with the four UTAUT constructs to influence the BI (Srivastava & Bhati, 2020) within the UTAUT. These moderation components of the UTAUT can be compared to the internal and demographic factors of age and education (experience) to be represented in the survey scale, which may influence behavioral intention toward IMD adoption. These constructs of the UTAUT give a reason for it to be used as a suitable framework for this study's purpose and research questions. The dependent variable of BI to use an IMD also finds applicability in the UTAUT. Since UTAUT is a consolidation of adoption theories, it has significant conceptual similarities with those theories. For instance, its SI is equivalent to the subjective norm in the TPB, performance expectancy and effort expectancy are similar to the perceived usefulness and ease of use under the TAM model (Bagozzi & University of Michigan, 2007; Morchid, 2020; Rahman et al., 2017). As a suitable framework for this study, UTAUT is a more comprehensive technology adoption model, and it intertwines with the TAM framework.

Because the purpose of this study was to provide a better understanding of U.S. patients' behavioral intention to adopt and use an IMD, the UTAUT model was applied. This study made use of Yeow et al.'s (2013) UTAUT-extension. Also, predicted was whether the PE variable would be mediated by variable PC as well as the expansion of the model to include the variable Attitude. Although attitude is not part of the constructs within the UTAUT, attitude was regarded, for the purpose of this investigation, a valuable element in the determination of the levels of approval towards IMD usage. Proposed by Yeow et al. (2013), the *anxiety* variable will not be included because stress does not emanate from the use of IMD when one voluntarily opts to use an IMD, i.e., voluntary use of technology. Venkatesh et al. (2003) stated that there is an indirect relationship between the anxiety factor and BI via effort expectancy (EE). Effort expectancy has also been sidelined from this investigation because the use of an IMD requires no added time or effort as patients carry the devices internally, and experts maintain the devices when needed.

Introduction to Research Methodology and Design

Mohajan (2020) stated that it is appropriate to apply a quantitative, non-experimental, correlational approach if the researcher is investigating constructs in their original form without manipulation, where SEM or other statistical analyses methods are used in measuring the extent to which two or more constructs are associated when there is no random allocation of subjects to groups. The quantitative methodology was suited to my research because the research aimed at establishing the extent of the relationship between constructs in their original form without manipulation as the independent and dependent variables (Moote et al., 2020). In a quantitative, correlational study, Guan et al. (2022) involved the retrospective study of real-time observations of vaulting using the RESCAN 700 system. Using quantitative magnetic resonance imaging, Saccenti et al. (2020) performed a correlation study to compare the various imaging techniques in multiple sclerosis patients. Pairwise correlations were calculated using Spearman's correlation analysis. According to Alberts et al. (2020) and Mohajan (2020), when the aim of the study is the testing and verification of theories to generalize and replicate the results in other subjects and environments, the quantitative method is more suitable.

In a similar IMD study, Madjid et al. (2019) studied the effect of high influenza activity on risk of ventricular arrhythmias (VA) requiring therapy in patients with implantable cardiac defibrillators (ICD)s and cardiac resynchronization therapy defibrillators. Significant correlation was found between the influenza activity and the incidence of VAs requiring ATP treatment. Menebo (2020) conducted a quantitative correlation study to analyze correlations between the weather and the COVID-19 pandemic in Oslo, Norway, where a non-parametric correlation test was performed during data analysis. A non-experimental, correlational, quantitative approach was the most appropriate for conducting this study because none of the independent variables (Att, PC, PE, SI, and FC) was manipulated to identify their influence on the DV, BI to use an IMD. Moreover, the study evaluated the mediation of predictability for the predictor construct of PE by the mediating construct of PC.

Data was collected using the adapted survey instruments mentioned beforehand. The research instrument items were adapted from the instruments developed by Yeow et al. (2013, see Appendix B); Kohnke et al. (2014, see Appendix C), and Morosan (2016; see Appendix D). This survey allowed for the collection of data from a large enough sample obtained from Facebook users residing in any of the 50 states within the United States and belonging to IMD support groups on Facebook. Permissions were sought through emails and Facebook Messenger to the respective administrators of the relevant IMD support groups on Facebook.

Once permission was granted from the group moderators, permission was requested by this researcher from the Northcentral University (NCU)'s Institutional Review Board (IRB) for data collection. Once IRB approval was obtained, invitations to group participants was posted together with informed consent details (see Appendix E). The survey responses were transmitted into Excel files which were subsequently loaded by this researcher into SPSS for data analysis. SEM within SPSS AMOS version 26 software was used to both access and assess the variables under consideration, as well as used in performing correlational, factor analyses, SEM, and path analysis.

Research Questions

The following six research questions emanated from the theoretical framework of the UTAUT model and the study's purpose.

RQ1

What is the degree of relationship, if any, between Attitude and U.S. patients' behavioral intent to use an IMD?

RQ2

What is the degree of relationship, if any, between performance expectancy and the U.S. patients' behavioral intent to use an IMD?

RQ3

What is the degree of relationship, if any, between facilitating conditions and U.S. patients' behavioral intent to use an IMD?

RQ4

What is the degree of relationship, if any, between social influence and U.S. patients' behavioral intent to use an IMD?

RQ5

What is the degree of relationship, if any, between perceived credibility and U.S. patients' behavioral intent to use an IMD?

RQ6

What is the degree of relationship, if any, between performance expectancy and U.S. patients' behavioral intent to use an IMD when accounting for perceived credibility?

Hypotheses

The six null and six alternative hypotheses with direct correspondence to the six Research Questions above are as follows:

$H1_0$

Attitude is not a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD

$H1_a$

Attitude is a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD

$H2_0$

Performance Expectancy is not a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.

$H2_a$

Performance Expectancy is a statistically significant predictor of the U.S. patients' behavioral intent to use IMD.

$H3_0$

Facilitating conditions is not a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.

$H3_a$

Facilitating Conditions is a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.

$H4_0$

Social Influence is not a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.

$H4_a$

Social Influence is a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.

$H5_0$

Perceived credibility is not a statistically significant predictor of the U.S. patients' behavioral intent to use an IMD.