

The Gap in Medical Technological Advancement and Procurement Management

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ABSTRACT

The fourth industrial revolution has become the forefront of advancement in medical devices technology. The key intention of this study is to identify the growing gaps created on procurement management system due to the speed of technological advancement in medical devices. This is a narrative overview of the literature review on an existing online database and published articles. It is an overview of the impending existence of gaps between medical devices advancement and procurement work processes. The findings expected to uncover the elements that would influence procurement work processes in terms of speed and ease in sourcing and buying the right thing, at the right time and the right price. The compilation of information expected to provide the importance of matching the velocity of the procurement work process in line with medical devices advancement for the benefit of patient care delivery. This would provide outlook and awareness to the healthcare stakeholders, especially to the management team on the implications of continuous delay as well as the urgency to upgrade the procurement management system because of the speed in treating patients is getting quicker.

INTRODUCTION

The fourth industrial revolution (IR4.0) has become the forefront of advancement in medical devices innovation. The fourth

industrial revolution is a movement towards empowering people through digitalizing current approach in doing things and connecting devices. Healthcare industry is amongst the sector that has been quick in utilizing the benefit of IR4.0 technological pillars, such as Artificial Intelligent (AI), Internet of Thing (IoT), Big Data and Analytics as just to name a few. This statement was further supported by a team of 622 business leaders from diversified industries from all over the world have undergone pooling in January 2016. The outcome shows a significant prevalence that at 45%, healthcare sector would most benefit from the innovation (Swabey, 2016), followed by finance and energy sector at 15%, infrastructure at 14% and finally education sector at 11%. Subsequently, medical device connectivity through the technological pillar of IoT is predicted to grow at CAGR 38% in the next five year (Lobo, 2017).

Nonetheless, the term of the fourth industrial revolution develops awareness in Malaysia during the World Economic Forum in the year 2016 (Bernama, 2018). the rapid change in the medical industry requires procurement management processes to change in line with IR4.0 mobilization. The medical device comprises of “instrument, apparatus, implement, machine, appliance, implant, the reagent for in vitro use, alone or in combination,” for diagnostic, monitoring, prevention, treatment and sustaining life (World Health Organization, 2003). Even simplest items such as cotton, to complex equipment such as robot surgical machine, all fall under medical devices. Hence, the innovation of medical devices not only on equipment but also on medical supplies and implantable devices. The aspect of time, cost and quality of healthcare has much been discussed by other researchers. Procurement functions significantly affect the overall speed and efficiency of an organizations supply chain activities. This makes procurement management as the most valuable part of supply chain management (Ahmadi, Pishvae, & Torabi, 2018) as well as for the healthcare industry.

Procurement management or function was lacking importance at the organizational level until the 1800s (Nolan, n.d.). Purchasing function started gaining its importance during the industrial revolution phases. Procurement today no longer just doing a clerical task, nor basic buying and sourcing lowest product price. Procurement management now plays a strategic role in supporting the organization’s strategic planning development and actively support the organization’s goal. Darr (2019) has clearly explained procurement management by correlating the terms of the industrial revolution (IR). Procurement 1.0, correlation to IR1.0; is a one to one issuance of a purchase order from buyer to a seller. Followed with Procurement 2.0 is the repetition of buying and replenishment of stock. Subsequently, in Procurement 3.0, purchasing procedures, stock replenishment and back to back order was now done electronically using Enterprise Resource Planning (ERP) and E-Procurement software. Finally, in this current industrial revolution, Procurement 4.0 enable analyses, prediction, deciding, controlling and digitalizing the procurement procedures from clerical task to automatic, real-time connectivity and smart functionality (Darr, 2019).

At present, the procurement team expanded its role as a contributing factor to the success of organizations. New purchasing software has continued to evolve, and the procurement team need to look into adopting a new procurement management system to level up their current processes against the speed of medical devices’ innovation. And so, what are the dimensions that emerge to augment the focus of this concern?

METHODOLOGY

This paper employs systematic literature review (Green, Johnson, & Adams, 2006) accepted guidelines which include the eligibility criteria, search process, study identification, quality assessment, and data analysis. The review procedure searched for

no specific study design and utilizes the TOE framework (Eveland & Tornatzky, 1990) that stands for “technological, organizational and environmental” as the main constructs in the identification of gaps on procurement management system as a result of medical device innovation.

Eligibility Criteria

The review was systematized to include all published articles between the year 2015 and 2019. Articles selected is in the English version and excluded books and news. The articles that were included contained (1) purchase or

procurement, and (2) hospital or health, and (3) medical innovation or medical technology. While articles that focused on (1) medicine innovation or (2) missing either of the inclusion criteria is excluded from this study.

Search Process

The search process was executed using google scholar that is sorted by relevance. The searching is based on the wording “purchase”, “procure”, “medical”, “innovation”, “hospital”, “health”, and “technology”. Type of articles shortlisted consist of a journal article, policy brief and commentary to extend the findings of a gap and the percentage by country of study (see Table 1 below).

Table 1 Selected online database

Year	Type	Journal / Source	Country
2019	Journal Article	Journal of Health and Translational Medicine	Malaysia
2019	Journal Article	Therapeutic Innovation & Regulatory Science	Europe
2018	Journal Article	Health Economics, Policy and Law	Russia
2018	Journal Article	Journal of Medical Internet Research Publications	USA
2018	Journal Article	International Journal of Technology Assessment in Health Care	Canada
2018	Journal Article	International Neurourology Journal	Korea
2018	Journal Article	Advancing Safety in Health Technology	Oman
2018	Journal Article	International Journal of Technology Assessment in Health Care	Canada
2018	Journal Article	Advancing Safety in Health Technology	USA
2018	Journal Article	Scandinavian Journal of Management	Sweden
2017	Journal Article	American Journal of Medical Quality	USA
2017	Journal Article	Journal of Purchasing and Supply Management	UK
2016	Policy Brief	Health Systems and Policy Analysis	Europe
2015	Journal Article	International Journal of Operations and Production Management	Europe
2015	Commentary	Health Affairs	USA
2015	Commentary	C.D. Howe Institute	Canada
2015	Journal Article	European Journal of Operational Research	Czech Republic
2015	Journal Article	British Medical Journal	UK

Study Identification

There were 41 articles extracted into Mendeley reference management software program. All abstract, findings and conclusion were reviewed, and 18 articles were selected

that have at least the paired descriptors of “purchase/procure”, and paired with “medical innovation/technology”, or paired with “hospital”. All type of research design was included in the inclusion criteria as to widen the exploration scope of review.

Quality Assessment

The Mixed Methods Appraisal Tool (MMAT) was used to assess the quality of the selected articles. This tool can assess diversify research design: quantitative, qualitative, randomized controlled trials, non-randomized and mixed-methods. It is also easy to use tool to assess the quality of studies. However, the quality assessment was not performed to gain better result (Gagnon, Desmartis, Poder, & Witteman, 2014) due to the nature of this review aimed at exploring studied gap. Moreover, this tool cannot be used for non-empirical papers such as review (Hong et al., 2018). Therefore, MMAT quality assessment will not be able to entirely assess the selected articles (see Table 1 above) for this study. Also, there are no strict guidelines (Green et al., 2006) of the content to include a quality narrative overview.

Data Analysis

The extracted data were collected to focus mainly on the findings and the future research

eliciting the core constructs of Technological, Organizational and Environmental framework of Tornatzky and Fleischer (1990). Given the diversity of the content of the gap identifications, hence, a narrative synthesis on the results of the selected articles was conducted for this study.

DISCUSSION

The total search result was about 16,900 and only 41 articles were extracted into Mendeley reference management software program based on the identified inclusion criteria. All abstract, discussion, findings and conclusion were reviewed, and 18 articles were selected that best fit according to TOE construct (Figure 2 below). This may well facilitate in recognizing the greater view of dimensions that influence strategic decision making of innovation adoption. Therefore, the construct is appropriate to utilize in this study for identifying the gaps in procurement management corresponding to the healthcare industry innovation.

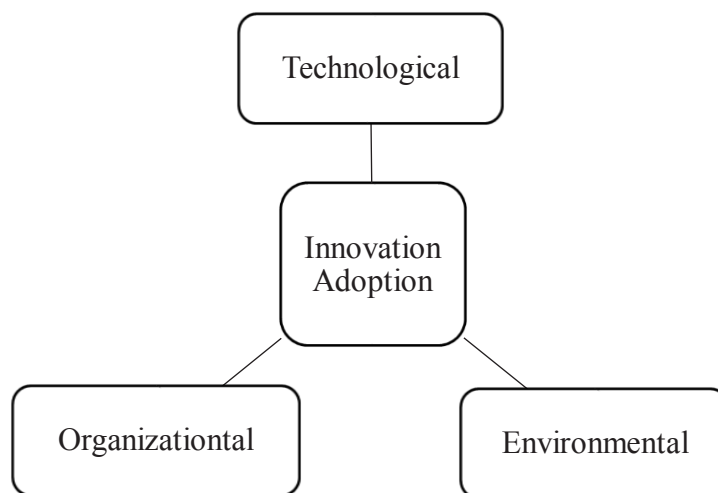


Figure 1 Technological, environmental and environmental (TOE) framework

Technological Factor

The technological factor of TOE framework refers to both internal and external influence on organization in terms of their perceived usefulness, perceived compatibility, perceived complexity, and relative advantages (Premathilaka & Fernando, 2018; Awa & Ojiabo, 2016). Through the paper review, it was found that the procurement and tendering process is crucial in ensuring sustainability (Messori, Trippoli, Caccese, & Marinai, 2019). Tendering process normally used in procuring high-value items especially healthcare-related devices that can cost millions of dollar such as MRI machine, CAT scan machine, just to name a few. Tendering process approach now would not be the same as in the future. Messori, Trippoli, Caccese, & Marinai, (2019) stated that the tender process requires to align with a value-based method and cost-effectiveness principles of innovation, as well as quality and value into calculating of the tender score (Messori et al., 2019; Miller et al., 2019; Meehan, Menzies, & Michaelides, 2017). It is given that the safety aspect (Doyle & Vockley, 2018) of a device is vital for patient safety apart from cost, risk and quality management (Al-Mawali, Pinto, & Al-Hinai, 2018). Nonetheless, an innovation of medical devices must also generate solutions that suitable for local needs (Al-Mawali et al., 2018) and reduce the training burden (Doyle & Vockley, 2018) toward hospital stakeholders (physicians, nurses, biomedical engineers, purchasers and even suppliers) to overcome the challenges of rapid changes and complexity of medical technology development. Hence, the new procurement management system must be flexible enough that the online tender and procurement process is easy enough to be upgraded in line with the current and future required feature in the calculation the cost-effectiveness of procuring new medical devices.

It is also unavoidable that in certain circumstances, the purchase of medical devices was executed under some aspect of uncertainty due to lack of information or information given were not accurate. In this context, in a separate study suggested that a system to support the uncertainty of decision making to purchase medical devices should include the factors of clinical effectiveness, patients' preferences on treatment choices, the purpose of medical application, ease of usage, safety and reliability features, requirement on maintenance, the total cost of ownership, and terms and conditions of the sales agreement (Ivlev, Vacek, & Kneppo, 2015; Polisen et al., 2018).

Refer to Table 2 below, it is obvious that the current procurement management system is still lacking data and work process synchronization as it is still organized offline due to challenges on system customization. While experts continue to look for a better approach in formulating the best practice of purchase decision-making process, the procurement management system should not confine to the stated dimensions of perceived usefulness, compatibility and complexity. It is important to include the dimensions of ease in system customization to avoid from the current system to have a barrier in upgrading due to the unreasonably high cost and system rigidity that would lead to a hindrance to improving. By having an online cohesive procurement management system for all, not only does it promote purchase transparencies; it also ensures vital steps are configured into one system to promote best practices and avoids omission in decision-making steps. Utilizing online cohesive procurement management system for all will enables the required information being compiled and taken into considerations to generate calculated purchase evaluation that beneficial in strategic decision-making processes

Table 2 Selected articles on technological constructs

Authors	Journal	Title	Significance
Messori, Trippoli, Caccese, & Marinai, 2019 (Europe)	SAGE Journals	Tenders for the Procurement of Medical Devices: Adapting Cost-Effectiveness Rules to the Requirements of the European Public Procurement Directive	“Tenders should conform not only value-based methods and cost-effectiveness principles, but also the scores for quality and price” (p.6).
Miller et al., 2019 (Canada)	International Journal of Technology Assessment in Health Care	How Procurement Judges the Value of Medical Technologies: A Review of Healthcare Tenders	“Procurement brings a distinctive approach to the evaluation of medical technologies, with consequences for cost, quality and innovation” (p.5).
Al-Mawali, Pinto, & Al-Hinai, 2018 (Oman)	Biomedical Instrumentation & Technology	Medical Equipment and Healthcare Technology: Health Vision 2050	“Life cycle of MEHT must be overseen by governance systems for the asset, cost, risk, and quality management in developing solutions appropriate to local needs” (p.1).
Polisena et al., 2018 (Canada)	International Journal of Technology Assessment in Health Care	Health Technology Assessment Methods Guidelines for Medical Devices: How Can We Address the Gaps? The International Federation of Medical and Biological Engineering Perspective	“Improvement in Hospital Technology Assessment includes product lifecycle, clinical evaluation, issues in use, and costs and economic evaluation” (p.287).
Doyle & Vockley, 2018 (USA)	Biomedical Instrumentation & Technology	Overcoming User-Centered Challenges with Complex Health Technology	“These user-centred patient safety issues can be addressed in good part by improved design for usability and better approaches to Procurement” (p.28).
Meehan, Menzies, & Michaelides, 2017 (UK)	Journal of Purchasing and Supply Management	The long shadow of public policy; Barriers to a value-based approach in healthcare procurement	“Stakeholders across the supply chain shared a clear view on what value-based approaches could achieve, and the focus for improvement centred on patient outcomes, collaboration, and total cost across a supply chain” (p.6).
Ivlev, Vacek, & Kneppo, 2015 (Czech Republic)	European Journal of Operational Research	Multi-criteria decision analysis for supporting the selection of medical devices under uncertainty	“An analytic hierarchy process (AHP) take into account a wider range of selection criteria, such as the clinical effectiveness, patients’ preferences, medical purpose of an application, ease of use, reliability characteristics and safety, maintenance requirements, the total cost of ownership, and sales contract terms and conditions” (p.10).

Organizational Factor

Subsequently, the organizational factor in TOE framework generally measures the organization scope of the business, top management support, manpower knowledge, organization culture, and size of an organization (Premathilaka & Fernando, 2018; Awa & Ojiabo, 2016) in the adoption of innovation. Researchers found that hospital internal policy setting is not wholesome. In terms of the aspects of privacy and data security which is highly important to put in practices to protect patients and their family. However, research stated that hospital policies on security issues are more on data privacy to abide by the PDPA (Personal Data Protection Act) instead of data security (Jalali & Kaiser, 2018). While privacy on patients' sicknesses and interventions are highly private, the security level of the hospital database seems lacking importance.

Apart from data privacy and security policies, innovation policy should be considered during the procurement processes. Product specifications and requirements that is loosely composed will impart perception that only the cheapest product is being considered which leads to wrong procurement indicator (Askfors & Fornstedt, 2018). The

poor approach in gathering information, inadequate hospital technology assessment and priority positioning by hospital authority due to concerns on lack of funds (Shishkin & Zasimova, 2018) lead to inefficient adoption that not only have an adverse effect on the quality of the procured device but also directly impact the quality of patient care delivery.

Therefore, refer to Table 3 below, organizational awareness is another important dimension under the organization construct measures. Positive organizational awareness can proposition ideas from various point of view and proactively dealing with changes. Because data privacy is as important as data security in healthcare. Thus, data sensitivity policies are to incorporate into a procurement management system to mitigate risk. Additionally, universalism in organization culture guide employees to establish rules and obligations as a priority that offers clear instructions and processes to meet the condition of innovation policy within the organization. This is specifically advantageous in enhancing the effectiveness of procurement management in obtaining accurate product specifications and requirements, as well as gathering the correct information for technology assessment in making a purchase decision.

Table 3 Selected articles on organizational constructs

Authors	Journal	Title	Significance
Jalali & Kaiser, 2018 (USA)	Journal of Medical Internet Research Publications	Cybersecurity in Hospitals: A Systematic, Organizational Perspective	"Hospitals should set their target level of Cybersecurity beyond the requirements of current regulations and policies" (p.1).
Askfors & Fornstedt, 2018 (Sweden)	Scandinavian Journal of Management	The clash of managerial and professional logics in public procurement: Implications for innovation in the healthcare sector	"Formulating the requirements for a tender specification is a bottleneck for innovation diffusion" (p.88).
Shishkin & Zasimovaan inappropriate choice (in terms of economic and clinical parameters, 2018 (Russia)	Health Economics, Policy and Law	Adopting new medical technologies in Russian hospitals: what causes inefficiency?	"Medical technology procurement drawbacks could be observed during each step of decision making – poor information gathering, ambiguous procedures of technology assessment, and authoritarian in hospital priority-setting mechanisms" (p.14).

Environmental Factor

Finally, Finally, the environmental factor in TOE framework correlates with operational related enablers such as suppliers, competitors and government influences. The dimensions that mostly covered under the environmental factors would be competitive pressure, supplier readiness, and government support (Premathilaka & Fernando, 2018; Awa & Ojiabo, 2016). From the review of articles, external policies and regulations that meant to protect the public importance can, in turn, becomes an obstacle in improving patient care delivery (MacNeil et al., 2018) and hindrance towards procurement decision-making efficiency. For example, Medical devices pose unique challenges on economic evaluation (price, quality and availability) that associate in decision-making processes. To protect public safety and health, Ministry of Health Malaysia (MOH) has introduced the Medical Device Act 2012 (MDA). This act warrants all existing and new medical devices to undergo a comprehensive regulatory programme to prevent the sub-standard, unsafe and ineffective medical device from penetrating Malaysia market (Medical Device Authority, 2019). However, the process in getting the MDA certification seems to take longer cycle especially for more complex medical innovation and the add-on cost in getting the certifications to contribute to the delay in procuring process and consequently resulting to holdup toward diffusion of innovation.

Lack of co-operation with manufacturers, suppliers and policymakers causing unnecessarily increased in cost of medical devices, difficulties to access innovation, the inconsistency of data, inefficiency in managing supply, homogeneity in policies and processes, biased in technological evaluation by stakeholders, failure to identify needs against wants, and rushed purchases leads to tension in a relationship; creating a gap in the procurement management process of new medical devices.

Refer to Table 4 below, it is noticeable that all parties beginning with the manufacturers, and, suppliers or distributors required to undergo medical devices certifications such as CE (Conformité Européenne) marking, MDA certification and FDA (Food and Drug Administration) approval. These are amongst the common requirements to ensure usability and safety aspects of the innovated devices are met before the hospital can procure it. Taking everything into account, the overall focus in terms of the environmental construct is collaboration and partnership with external enablers. The selected articles highlighted ethical and social importance (Choudhury, 2019), the stability of supply chain management (Lee et al., 2018), cross-border collaboration (Espín et al., 2016), aligning strategies with suppliers (Gobbi & Hsuan, 2015); Doyle, Gurses, & Pronovost, 2017), collaboration with policymakers (Robinson, 2015), collaboration with stakeholders in technology evaluation (Pinna, Carrus, & Marras, 2015) and cooperative partnership between hospitals and suppliers (Cresswell et al., 2015). Through collaboration and partnership, accessibility to supply and innovation would be more effective.

Table 4 Selected articles on environmental constructs

Authors	Journal	Title	Significance
Choudhury, 2019 (Malaysia)	Journal of Health and Translational Medicine	Modern Medical Devices and Hospital Decision Making: A Review of Ethical and Social Considerations During Manufacture and The Use of Advanced Medical Devices	"Bioethical standards needed to ensure safety and maintenance of the quality of life among users" (p.6).
Lee et al., 2018 (Korea)	International Neurourology Journal	Innovative Distribution Priorities for the Medical Devices Industry in the Fourth Industrial Revolution	"It is necessary to establish a stable supply system and manage crises through supply stability, as well as to provide opportunities for fair trade through greater transparency, efficiency, smart supply, and cost reduction" (p.589).
Doyle, Gurses, & Pronovost, 2017 (USA)	American Journal of Medical Quality	Mastering medical devices for safe use: policy, purchasing, and training	"Collaboration to overcome poor usability of devices and haphazard training and competency assessment" (p.101).
Espín et al., 2016 (Europe)	Health Systems and Policy Analysis	How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe	"Cross-border collaboration in public procurement of health technologies can be facilitated by ownership, equity, transparency, flexibility, standardization and gradual development" (p.20).
Gobbi & Hsuanthe paper identify factors for shareholder alignment (i.e. aligning the needs of the buyers within the purchasing group, 2015 (Europe)	International Journal of Operations and Production Management	Collaborative purchasing of complex technologies in healthcare: Implications for alignment strategies	"Aligning buyers' or shareholders' needs requires appropriate management of the relationships (i.e. promote trust and commitment), expertise and guidance in simplifying procedures and properly organize the purchasing group" (p.1).
Robinson, 2015 (USA)	Health Affairs	Biomedical innovation in the era of health care spending constraints	"Policymakers will need to accept technologies whose value lies in their affordability as well as quality" (pp.207-208).
Pinna, Carrus, & Marras, 2015 (Canada)	C.D. Howe Institute	Emerging Trends in Healthcare Supply Chain Management: An Italian Experience	"Collaboration in HTA frameworks encourage greater stakeholder participation and relationship development by conducting in a neutral manner and be reasonably immune from politics, public pressure and media advocacy" (p.19).
Cresswell et al., 2015 (UK)	British Medical Journal	Qualitative analysis of vendor discussions on the procurement of Computerised Physician Order Entry and Clinical Decision Support Systems in hospitals	"Strained relationships need to be more effectively managed by drawing on more sophisticated strategies from other industries that may include proactive approaches that allow cooperative partnerships between hospitals and vendors" (p.8).

CONCLUDING REMARKS AND FUTURE WORK

In conclusion, globalization has evolved the procurement task as one of the strategic functions of an organization. Procurement management not only mere sourcing, negotiating and bringing in goods and services required. However, the task involves commercial analysis, evaluating and comparing goods and services that best fit the organization's requirement, and projecting future needs. Innovation in the healthcare industry is moving at a rapid pace. The uses of artificial intelligent (AI) and internet of thing (IoT) have brought benefit to society as AI could detect lung cancer (Sandoiu & Godfrey, 2019) and predict psychosis risk (Paddock & Godfrey, 2019) compared to a human. Even mobile health applications are flourishing as it is gaining popularity among smartphone users. However, the effectiveness of the applications has been in questioned (Whiteman, 2014) and can it help to improve health outcome (Collier & Ellis, 2018). Thus, it is a great challenge in

deciding on the purchase and utilization of these devices and applications. Risk has been and will be the main headache in procurement management, and this becomes greater concern since the cost involves is not only high but most importantly, it concerns with patients' life expectancy.

For that reason, refer to Figure 2 below, procurement managers need to keep up the pace of medical innovations by ensuring that their procurement management system is easy to customize in line with the growing importance that needs to be evaluated to minimize the risk of procuring innovation under uncertainty. Whereas, internal stakeholders and leaders within the organization to inculcate the organizational awareness and universalism culture so that the information gathered from all internal stakeholders would be as accurate and wholesome. Finally, it is high time to find the balance in collaborating and partnering with the external stakeholders to bring values and thereafter create competitive advantage.

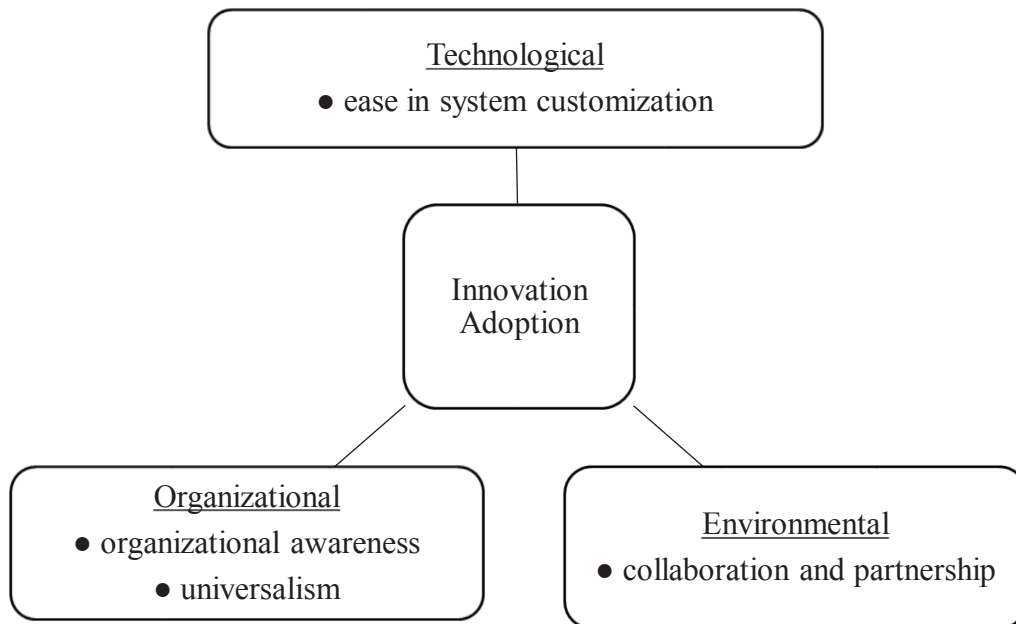


Figure 2 Technological, Environmental and Environmental (TOE) Dimensions

Patients and consumers not only looking for quality, safety, and price transparency but also a less pain and fast recovery surgical approach from the healthcare organization. Nonetheless, these resulted in the high cost of treatment due to the hefty sum in procuring these sophisticated medical devices in meeting the demand for premium healthcare service. Therefore, further study using the TOE framework should include the above dimension when adopting procurement innovation.

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