

THE ANALYSIS OF APPLICATION OF ISO 55000 CONCEPTS IN HOSPITAL CONTEXT: THE CASE OF CT SCANNER LIFE CYCLE MANAGEMENT IN A QUEBEC PUBLIC HOSPITAL

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ABSTRACT: *The purpose of this article is to analyze the adoption of the concepts of ISO 55000 standard in a hospital biomedical context. It focuses on a case study with a qualitative content analysis of life cycle management practices of a CT scanner (Computed Tomography scanner) in a Quebec public hospital. The results of this analysis show that there are consubstantial paradigms in hospital settings which are like "modelators" that distinguish the approach of application of the ISO 55000 standard concepts for the management of hospital biomedical physical assets.*

KEYWORDS: *Physical assets management, ISO 55000 concepts, Health care technologies management, Hospital CT scanner life cycle management.*

1 INTRODUCTION

Healthcare organizations face many challenges nowadays and are under increasing pressure to ensure quality health care effectively and efficiently (Hellstrom, Lifvergren et Quist, 2010). Despite these many challenges, including those of managing their biomedical physical asset, their goal remains to ensure a quality of continuum of care whenever and wherever it needed (Chris et al., 2011) (Brown et Smale, 2007) (John et al., 2015).

The sine qua non condition to ensure the safety and diagnostic services, treatment, monitoring and treatment of patients in a suitable care setting, is good management of health technologies (Organisation mondiale de la santé, 2012). The three essential goals in the management of medical physical assets (health technologies) are: to ensure that they meet the appropriate needs of clinical services, they function efficiently and safely, and that they represent a value investment (Keith, Keith et Slavik, 2013). In other words, it is necessary that hospitals take the necessary measures to ensure the prevention of damage, to patients to the users and also the preservation of environment, by ensuring the proper functioning of their medical physical assets (Chien, Huang et Chong, 2010).

With this increasing pressure faced by healthcare organizations (hospitals) to improve their operations and to provide proof of their quality and efficiency, the man-

agement techniques evolved from the industry sector propagate within hospitals (Hellstrom, Lifvergren et Quist, 2010).

Like these management techniques from the manufacturing sector, the new standard ISO 55000 is intended to be a standard for optimizing the management of all physical assets of any size and any type of organization (ISO55000, 2014a). But the hospital biomedical context differs from other forms of industries and has special features for the adoption of management techniques evolved from the industrial context (Hellstrom, Lifvergren et Quist, 2010) (McCarthy et al., 2014) (Chang Won et Kwak, 2011; Suebsin et Gerdri, 2010).

In such a hospital context, will applying the concepts of the ISO 55000 standard face barriers as far as hospital medical physical assets management is concerned? Will applying the concepts of the ISO 55000 standard for the management of hospital biomedical physical assets require a special approach?

In this article we have made a qualitative content analysis in an inductive approach, of collected materials which describe the life cycle management practices of a CT scanner (Computed tomography scanner) in a Quebec public hospital, to analyse this question.

2 THE CONCEPTS OF ISO 55000

An asset is something that has actual or potential value for the organization. (Davies, 2014). Since the 80s, the concept of physical assets management appeared within companies, has grown mature nowadays, despite the fact that each company has its strategies to achieve its objectives (Lloyd, 2012). The appearance in 2004 of the first release of PAS 55 (Publicly Available Specification), a collection of best practices in management of physical assets, promoted by the IAM (Institute of Asset Management et British Standards Institute) and BSI (British Standard Institute), has redefined the concept of managing physical assets, which historically has been confused with a set of independent activities covering operations and maintenance of equipment (Zhuang et al., 2011).

The new ISO 55000 standard formally defines the physical assets management as "a coordinated activity of an organization to realize value from its assets." (ISO55000, 2014a). Particularly, it defines key concepts characteristics of its adoption within any organization. A number of concepts were raised in committee discussions when developing International standard ISO 55000 (Torrence et al., 2014). Going through the books of ISO 55000 standard, these concepts are well defined on the basis of some statements. By a qualitative and a quantitative analysis of ISO 55000, the concepts of the application of ISO 55000 have been described by industrial experts panel who served on the committee that seat for the development of the ISO 55000:2014 (Torrence et al., 2014). These concepts are described as follow:

2.1 The concept of " value " versus performance

'Assets exist to Provide value to the organization and its stakeholders' (ISO55000, 2014a). However, asset management does not focus on the asset itself, but on the value that it can provide to the organization (ISO55000, 2014a). In other words, asset management should focus on the contribution of assets to the organization's mission and not simply on its performance which, traditionally, represented the final financial outcome sought by the company, even if performance remains a component of the value (Torrence et al., 2014). Performance management is maintaining an acceptable level or service in the most cost-effective way (Gay et Sinha, 2013). Also, performance of the assets are the baseline for an asset management program (Pedicini et al., 2014). Thus, performance of an asset defines how the asset condition changes over time or how well the asset serves its intended functions with accumulating use (Dehghani et al., 2013).

2.2 Strategic Alignment Concept

'Asset management translates into the organizational objective, technical and financial decisions, plans, and

activities' (ISO55000, 2014a). Strategic alignment also means that the 'asset management objective, included in the strategic asset management plan (SAMP) 'shall be aligned to and consistent with the organizational objective' (ISO55000, 2014b). In other words, in most organization, asset management strategy may be different from organization strategy but must support the organization to achieve its objective (Torrence et al., 2014). So, with the adoption of ISO 55000, an efficient and effective management of assets must help organization to accomplish its objective (ISO55000, 2014a) (Torrence et al., 2014).

2.3 Life cycle management of assets versus management following a triennial, quinquennial or a program

This concept allows to focus on integrating management across the lifecycle of the asset versus using the traditional management approach based on a three-year or five-year plan (Torrence et al., 2014). In other words it allows management of assets, according to their life cycle and aligned with the policy, strategy and business goals, in a long-term vision (strategic dimension) and not following a short vision term (tactical) and medium term (operational aspect) (Zhuang et al., 2011).

2.4 'Line of Sight' Concept

According to Torrence et al. (2014), this concept reflects a clear vision, in both directions, between the top management on one hand and the use and performance of the assets of the other. In other words, it reflects the recognition of the importance of assets by the top management that the vehicle to a lower level of the organization through its policies and plans. Conversely, it also means the possibility of transmission by the lower level of the organization, ideas and asset management activities to the top management (Torrence et al., 2014).

2.5 An acceptable level of risk versus opportunities

For asset management, international standard ISO 55000 applies the definition of risk as described by ISO3100-2009-Risk Management Principles and Guidelines (Torrence et al., 2014). Opportunity may be presented by the existence and status of an asset or asset management system created by asset management system (Torrence et al., 2014). 'Asset management does translate the organization's objectives into asset related decisions, plans and activities, using a risk-based approach' (ISO55000, 2014a). In other words, asset management should not simply focus on the opportunities, but it must integrate an acceptable level of risk in the strategic plan asset management (Torrence et al., 2014).

2.6 Leadership Concept

'Leadership and workplace culture, are determinants of realization of value' (ISO55000, 2014a). Asset management leadership can be demonstrated by top management through positively influencing the organization and may appoint an individual to oversee the development, implementation, operation and continual improvement of an asset management system (ISO55000, 2014c).

3 HEALTH CARE TECHNOLOGIES LIFE CYCLE

The health technologies are "application of knowledge and skills organized in a form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. The health technologies and health care technologies are interchangeable" (Organisation mondiale de la santé, 2012). According to Cheng et World Health Organization (2003) the life cycle of health technologies is as described in Figure 1. It is a set of phases. Some are manufacturing phases and others are hospital phases. Those phases together perfectly fit the life cycle phases of physical assets as described by the ISO55000 (2014c) which are succinctly: design/acquisition, use, maintenance and renew/replace.

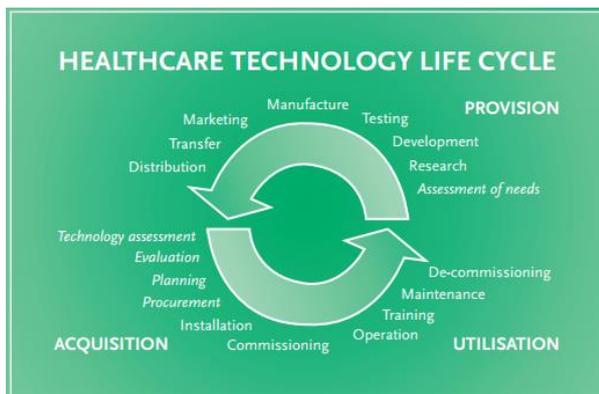


Figure 1 Healthcare technology lifecycle
(Cheng et World Health Organization, 2003), p.44)

4 RESEARCH TOPIC

Practices do exist in the optimization approach of the management of hospital medical physical assets. Many studies have tried to find solutions to optimize the management of medical physical assets, but there have some limits.

In a proposed management plan optimization of some very expensive medical assets like CT scanner (Computed Tomography scanner) and MRI (Magnetic resonance Imaging), Brown et Smale (2007) proposed, in a case study conducted in a large hospitals in Australia, a replacement prioritization and acquisitions over five years

for major medical physical assets. But the plan remains focused on only part of the life cycle of the asset.

Hossain et al. (2012), from their side, have suggested in a study conducted on medical imaging in a Bangladesh hospital, a structured management plan optimization of medical imaging equipment. The main components of this plan are: equipment management planning, maintenance management, management of equipment power supply, control of exposure to radiation, user training and monitoring of equipment operation and performance. This plan however does not incorporate the best practices of ISO 55000 standard. Same remark for Taghipour, Banjevic et Jardine (2011), who conducted in a case study in a Canadian general hospital on the analysis of the reliability of maintenance data of complex medical assets, have proposed an optimization model for inspection and maintenance physical assets. While Nagel et Nagel (2009) in their work have suggested indicators that allow to evaluate and measure the impact of infrastructure and health technology on service delivery and the quality of patient care.

However, the conceptual framework for health technology management process developed by McCarthy et al. (2014) on one hand, and the one proposed by Galeano, Cuartas et Escobar (2013) on the other hand, derive from the generic model of ISO 55 000. But they are not based on case studies and do not include a thorough analysis of the application of the concepts of ISO 55 000. So, to date, no case study analysis of the application of ISO 55000 on hospital medical physical assets and even less on CT scanners has been indexed in the literature.

The topic of this study is to analyze the transfer of physical asset management concepts as defined by ISO 55000, for the management of medical physical assets in the hospital biomedical field. Specifically, with qualitative content analysis method of life cycle management practices of a case of hospital medical physical assets, a hospital CT scanner, to determine whether this transfer of management concepts requires a special approach in the hospital setting.

5 MATERIALS AND METHODS

5.1 Description of the research methodology used

Literature books of ISO 55000 as well as the collection of analyzes of the implementation of the ISO 55000 standard conducted by a panel of experts who sat for the development of ISO 55000, allow to draw out and generally describe the different concepts of the concept of the application of ISO 55000. Then we made a qualitative content analysis in an inductive approach to analyze the life cycle management practices of a CT scanner in a Quebec public hospital.

It is an intrinsic case study as described by Fortin et Gagnon (2010) (p.279), because our goal is to have a better understanding of the case studied by carefully re-

leasing material facts to the case, while abandoning the other aspects.

Given the confidentiality of non-disclosure agreements of these data, we refrained to mention them in this article. However, the categories created and the results of this content analysis were validated by the actors involved in managing the life cycle of the CT scanner studied.

5.2 Description of the case and its context

The study site is a Quebec public hospital with over 500 beds including its technical platform which is on the cutting edge of technology. It serves a pool of 668,000 people. Its accessibility has been facilitated by the Department of Biomedical Engineering (GBM) who was very pleased to acquire the study. The case study focuses on a CT scanner with 128 slices (2x 64 slices) installed and put into operation in 2014.

5.3 Application of qualitative content analysis process used

Content analysis is a form of analysis among those called textual analysis which includes conversational analysis, ethnographic analysis, rhetorical analysis, functional pragmatic narrative semiotics (White et Marsh, 2006). There are two types of content analyzes: the qualitative content analysis (inductive) and quantitative content analysis (deductive) (Elo et Kyngäs, 2008) (White et Marsh, 2006) (Seuring et Gold, 2012). According to White et Marsh (2006), the content analysis is a research technique for making replicable inferences (that is to say, perfectly reproducible identically) and valid from a text (or other significant material) contexts of use. The notion of inference here reflects the approach of the researcher of using analytical constructions or inference rules to switch from the text, responses to the research questions (White et Marsh, 2006). The content analysis methodology is flexible by design and methodology of sensitive content (Elo et Kyngäs, 2008). In fact, in the content analysis, the researcher makes inferences and draw conclusions through independent textual domain to another which is the context (White et Marsh, 2006). In the phase of collection and the study of data analysis, the method used in this article is the qualitative content analysis. Applying the approach of a qualitative content analysis as described by Elo et Kyngäs (2008), Seuring et Gold (2012), and White et Marsh (2006), we performed the following different steps:

5.3.1 First step: collection of material or sampling

This step involves the selection, the definition of the material and the definition of the unit of analysis (Seuring et Gold, 2012). The data collected as part of a qualitative content analysis include for example: the current theories or practices; experience or expert

knowledge; data from previous research (White et Marsh, 2006).

In this study, the data types are composed of any document of life cycle management practices of the CT scanner under study, collected in the hospital (the study site) database. These documents recount the management practices management of all phases of the life cycle of the CT scanner studied. They include documents bearing on: the acquisition process, the feasibility study - design, the tender, purchase orders, drawings & specifications (mechanical, electrical, structural, architecture), plans and installation drawings, purchase receipt, acceptance of medical equipment, radiation protection inspection, service contracts, service reports, the three-year plan of asset maintenance, equipment specifications, risk management in radiology, the top management structure, organization of the radiology department, resource allocation for the acquisition process, the quality management.

5.3.2 Second step: material descriptive analysis

At this stage, the formal characteristics of the material are evaluated to define the context for subsequent content analysis (Seuring et Gold, 2012).

Clearly, we evaluated the material content by seeking formal characteristics that may allow us to identify the different categories according to content analysis material.

5.3.3 Third step: coding, selection of categories

Structural dimensions and related analytical categories are selected and applied to the selected materials (Seuring et Gold, 2012).

There are two choices to be taken when developing pattern of analytic categories: inductive and deductive category building, which correspond to the decision of what overall research approach (Theoretically grounded versus exploratory) (Seuring et Gold, 2012). In this study, we adopted an inductive approach (exploratory type). A manual structural decomposition and coding were performed, followed by the creation of categories shown as below.

Categories selected are:

- *Collaborative multidisciplinary*
- *Engineering and clinical knowledge*
- *Radiology clinical risk (Irradiation)*
- *Patient safety risk (Physical injuries)*
- *CT scanner life cycle funding*

5.3.4 Step Four: Material evaluation

During the fourth stage, an analysis of the material was made according to the analytical dimensions. It is a cyclical process applied to the contents of the selected equipment to ensure the internal validity and reliability of the categories and quality of research (Seuring, 2008) (Seuring et Gold, 2012). In other words, a challenge and a cyclical confirming the selection of categories was performed with a validation categories by asset management players in situ following the collected material.

6 RESULTS AND DISCUSSION

Results identified as R1, R2, R3, R4, R5 and their contents are highlighted as shown below:

R1: Organization of actors and their multidisciplinary collaboration: A collaborative multidisciplinary

- Membership of the Technical Analysis Committee, - Composition Prioritization Committee, - Composition of the Management Committee, - Composition of the applicants services (for acquisitions), - Composition of the Technical Services Directorate (DST), -Composition of the Department of Biomedical Engineering (GBM).

R2: Diverse notions of technological and non-technological knowledge: A combination of Engineering & clinical knowledge

- Architecture, - Electricity, - Electronics, - Mechanics, - Physiology, - Medical Physics, - Medicine, - Radiology, - Management, - Informatics.

R3: Monitoring of risks related to the patient's physical damage: A patient safety risk

Mechanical safety, electrical safety.

R4: The monitoring of risks related to radiation doses (dosimetry) and infection: A Radiology clinical risk

- Training of technologists on the patient radiation exposure parameters (milliamperere, kVp, irradiation time), - Calibration of irradiation parameters, infection controls.

R5: Financial Investment: CT scanner life cycle funding

- Budget vote by the Ministry (Government),
- Orders payment by the ministry, - Cost management by the hospital, - No return on investment (realization of non-profit vision)

From the above results, we interpreted in a double-analysis each result in relation to each category in confronting them in first hand, to existing literature but also

in the other hand in 'crossing' them with the concepts of the ISO 55 000 standard. This double analysis allows us to examine from the results of our case study, the existence or absence of factors that particularize or not, the adoption of the concepts of ISO 55000 in the hospital biomedical context.

6.1 Organization of actors and their multidisciplinary collaboration

The organization of the actors and their multidisciplinary collaboration directly affects the concept of leadership. "Leadership is a rational, collective, and purposeful activity based in the relationship of human motives and physical constraints between the power wielder and the power recipient" (Jennex, Smolnik et Croasdell, 2009). In other words, "leadership is characterized as the rational and purposeful human, risk taking activity focused on the positive evolution of an organization based on the social constraints between leader and follower" (Scovetta et Ellis, 2014). Thus, there is a 'leader' who is in power position and a power receiver who is the 'follower'

With collaborative multidisciplinary in hospital biomedical context, the concept of leadership claims a new form. Hospitals remain astonishingly fragmented industry (Herzlinger, 2006) characterized by a professional organization configuration that is to say, an organization based on skills in which there cannot have leadership (Mintzberg, 2012). Also, unlike a standardization of products and services in other industries, health care cannot be standardized from one patient to another, since the treatment of each patient is suited to its needs and his health. (Chang Won et Kwak, 2011) (Mintzberg, 2012). It therefore seems more appropriate to define an organizational structure here with a kind of mixed configuration: horizontal and vertical. The horizontal in one hand, reflects the high level directional collaboration between actors multidisciplinary committees where doctors are particularly in strong position, while the vertical translates the intrinsic level of the radiology department leadership model called collaborative or collaboration such defined by Crowe (2003). Also in this context, the strategic alignment and the concept of 'line of sight' as described earlier in this article by the ISO 55000 standard, requires special reformulation to include this reality of multidisciplinary collaboration that affects the leadership.

6.2 Diverse knowledge of technological and non-technological and funding investment mode

Lifecycle Management of the CT scanner under study reveals diverse knowledge in several areas grouped into two categories. In a first category we can designate in general industrial engineering knowledge grouping: physics, electronics, electrical, mechanical, architecture,

computers etc. In and a second category which we call 'Clinical group knowledge' and which includes physiology, medicine, biomedical, etc.

Thus, the management of hospital biomedical physical assets combines "clinical knowledge (a non-technological knowledge: physiology, medical, patient health, quality of health care, etc.)" and "industrial engineering knowledge (technological knowledge (mechanical, electrical, electronics, computer, industrial management, administrative management, etc.)" (McCarthy et al., 2014). If the technological complexity of industrial physical assets resulting in the combination of knowledge in general engineering, integration of clinical knowledge in the hospital biomedical physical assets technology is a noticeable difference. Thus, this combination of the clinical aspect and engineering aspect reflects the technological complexity of hospital biomedical physical asset that distinguishes them from other types of industrial physical assets (Chang Won et Kwak, 2011). This outstanding technological complexity is the basis of extensive information that combine clinical, financial and administrative activities which particularize the hospital field impeding the adoption of industrial management techniques for the management of hospital biomedical physical assets (Suebsin et Gerdri, 2010).

From, the results of our case study, it is also clear that the funding of the management of the lifecycle of the CT scanner under study is purely non-profit. The main goal is ensuring safe quality care to users. The goal is not to make huge savings on money invested as in for-profit organizations. The hospitals are non-profit organizations (Mintzberg, 2012) focused on the quality of care to be provided to the patient (McCarthy et al., 2014) while the profit organizations such as manufacturing, are focused on manufactured products and marketed to maximize their profit. (Suebsin et Gerdri, 2010).

So, hospitals are characterized by a non-profit funding which is responsible for the government and diversified intensive-information (technological, non-technological, administration, finances, etc.). In this context the concept of management covering the life cycle of the asset rather than following a three-year plan and a program promoted by ISO 55000 requires a special approach. Indeed, it would be necessary to plan an investment for the entire life cycle of assets by integrating the reality of the 'non-profit' while ensuring optimal operation to ensure safe care to the patient. It's sort of integral or sum of the three-year plans equal to the estimated life (depending on experience feedback or conceptual data) of assets whose non-profit investment is thought at the stage of SAMP (Strategic asset management Plan).

6.3 Monitoring of clinical risks (dosimetry) and patients risk (physical injury)

This study reveals the importance of risk management (dosimetry and physical damage) since the design and acquisition phase and during the useful life of this CT scanner studied.

The risks faced by computed tomography in patients are considerable. Although CT dose irradiated patients is minimal, it represents a risk factor for exposed patients (Tsushima et al., 2010). Despite the individual radiation dose, the risk of cancer deaths still considerable at high population level (de Gonzalez et Darby, 2004) (Einstein (Einstein, Henzlova et Rajagopalan, 2007). Studies have shown that UK from 2005 to 2006, about 60% of the total collective effective dose was radiology from CT (Hall et Brenner, 2014) (Tsushima et al., 2010). The contribution of the CT scanner to the effective dose for cancer patients from all X-ray systems in Germany from 2000 to 2005 is about 82% (Brix et al., 2009) (Tsushima et al., 2010). About 67% of the collective effective dose in diagnostic radiology was due to CT scanning in USA (Mettler Jr et al., 2000) (Tsushima et al., 2010).

These data clearly indicate that we cannot ignore the risks and clinical risk patients in the management of hospital CT scanners. These risks are sources of patient mortality and are controlled by stringent regulations of 'zero risk', while opportunity involves the lucrative aspect or huge financial benefit. So, is it appropriate in a hospital setting to express the 'risk' versus 'opportunities' by integrating an acceptable level of risk, as recommended in ISO 55000? It is necessary for the application of the concept 'risk versus opportunity' promoted by ISO 55000 used a particular approach, where clinical risks and patient risks are put above and clearly prioritized over any idea of opportunity.

In total, the transfer of knowledge from the industrial area to the biomedical and hospital sector faces several obstacles due to the organizational perspective of health care facilities, the nature of their labor, the characteristics of their labor of work, their relationships and their leadership control and performance measurement (Hellstrom, Lifvergren et Quist, 2010). Since differences of paradigms between health facilities and manufacturing industries justify this need for special approach to manage hospital biomedical physical assets. (Chang Won et Kwak, 2011). In the area of health, health care organizations work better as a vocation than as a for-profit enterprise, in that they require cooperation, not competition within its various players in these constituent institutions. (Mintzberg, 2012). In addition, the ubiquity of a contribution of technological and clinical skills (not technology) for the management of biomedical physical assets which are centered on patients (humans), differentiate them from industrial manufacturing such physical assets that are more focused on rigid objects (manufactured products, fruits, metals, etc.) reflecting

the " zero-risk 'items in the factory versus the risks and clinical risks to the patient considerable patients in the biomedical and hospital field.

Definitely, the generic model of the physical asset management process system described in ISO 55000 (PAS 55) is eminently applicable to the management of physical assets in general, but its application in the hospital biomedical field requires a special approach (McCarthy et al., 2014). In other words, there are consubstantial (distinguishable but inseparable) paradigms to the hospital biomedical context that require a special approach in the adoption of ISO 55000 in the hospital field. These paradigms are a kind of "modelators" for the application of the ISO 55000 standard concepts for the management of hospital biomedical physical assets.

7 THE CONTRIBUTION OF RESEARCH AND FUTURE RESEARCH

Our case study focuses on a content analysis of records of management practices of the life cycle of a CT scanner in a Quebec public hospital. It being understood that the diversity of: medical specialties, hospital biomedical physical assets variety as well as differences of objectives and management strategies from one hospital to another, it would be necessary to conduct qualitative and quantitative studies on other types of biomedical hospital physical assets. Qualitative and / or quantitative research on an implementation of the ISO 55000 concepts could help to better appreciate their adoption in a hospital biomedical context. However, this will require a longer time to be completed and can be done for future research.

The contribution of this research is that it helps to understand with a case study, that there are some consubstantial paradigms to hospital context which differentiate it to industrial context. This reflects the differences of paradigms between the industrial world and hospital world which affect and particularize physical asset management knowledge transfer from the former to the latter.

8 CONCLUSION

Consubstantial paradigms to hospitals settings differentiate them from other sectors of industries and particularize the application of the concepts of the ISO 5000 standard in the management of hospital biomedical physical assets. The contribution of this article is to highlight those consubstantial paradigms to hospital context when comparing them to industrial sector so as to aware hospital managers on the adoption of ISO 55 000 standard. This feature can slow or require a special approach of innovation management techniques evolved from the industrial world to be transferred into hospital context.

Finally, with the many challenges faced by managers of hospital biomedical physical assets outlined above in this article, an adoption of ISO 55000 management practices in the hospital biomedical context has many benefits which include; a cost saving, effective and efficient asset management; a clear vision of the park of hospital physical assets which have real or potential value; the popularization of ISO 55 000 standard adoption in hospital context which will facilitate a strategic alignment with local and national policy capacity and expected needs of the populations in health care; the improvement of the continuum of good quality of health care services which are secure and have fast access to populations; an implementation of agile services (flexible) which meet the variations of future health care services and which also fit the dynamics of the concept of sustainable development.

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