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MANAGING HEALTHCARE PROJECTS: comparing an OPEN AND CLOSED-LOOP technology implementation

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ABSTRACT

The healthcare sector is changing its traditional operations and services by deploying new technological innovations to better manage unpredictable events and supply accurate responses in time. However, because of the complexity of technological solutions and the complexity of the organizational conditions found in many healthcare institutions, most of the technological projects fail. This paper attempts to evaluate factors that could influence the success of ICT projects according to two different implementation modes: open-loop and closed-loop. Based on two study cases (end-to-end verification system and two-bins system for medicines inventory), we identified factors that affect both implementation patterns, some others influencing both models but having a deep impact on the open-loop implementation and factors that only hamper the open-loop strategy.

INTRODUCTION

Healthcare is one of the fastest growing business and largest service industries in the world *(Purbey et al., 2007)* but is an area of intense scrutiny in industrialized countries. In 2000, the Institute of Medicine estimated that the inadequate administration of medicines contributes to the death of 98,000 hospital patients in United States *(Institute of Medicine, 2000, p. 3)*. Approximately, one in every ten patients around the world has been harmed and killed by medical errors annually and the related cost from preventable errors could reach US$21 billion, a rather conservative estimate according to the National Quality Forum *(NPP, 2012)*. At the same time, many hospital facilities are currently challenged by staff safety concerns, financial pressure, and inefficient process management.

To face up to this situation, the healthcare sector should change its traditional operations by deploying new technological innovations to better manage unpredictable events and supply accurate responses in time *(Henjewele et al., 2013)*. Expanding the use of technology is one solution for reducing adverse events in healthcare entities *(Crane & Crane, 2006)*. However, because of the complexity of technological solutions and the complexity of the organizational conditions found in many healthcare institutions, most of the technological projects fail *(Al-Ahmad et al., 2009)*. With Information and Communication Technology *(ICT)* as a core component of many technological healthcare projects, the problem of ineffective project management is further exacerbated by the findings in recent reports indicating that only 28 percent of all IT projects are successful *(Shenhar and Dvir, 2007)*. It seems that the project management mode in healthcare is not natural and technology implementation is still little known.

This paper attempts to gain a better understanding of this under investigated issue. The objectives are twofold: 1) to identify the critical factors that could influence the success of technological implementation projects in healthcare industry and 2) to assess these factors in function of different technological adoption strategies *(open-loop versus closed-loop implementation)*. This paper is structured as follows: the next section presents an overview of technological project management in the healthcare industry. The second section presents the methodological strategy and the selected case studies. The third section presents and discusses the preliminary results while the last section offers some concluding comments and remarks.

1. Literature review

1.1 Healthcare context

Golden *(2006)* claimed that the most complex form of organizations is found in the healthcare sector. This is due to the number of stakeholders, multiple missions, decision makers with professional autonomy, and lack of information in managing technological and organizational transformations. Glouberman and Mintzberg *(2001)* studied the issues related to the professional bureaucracy in healthcare institutions. They showed that hospitals could efficiently coordinate their services by standardizing qualifications and speciality, such as emergency department, hospital pharmacy and pediatric department, among others. For these authors, the healthcare industry groups four professional entities that have different objectives and do not tend to collaborate between them. These groups are 1) the professionals involved in cure *(doctors)*, those responsible for care *(nurses)*, those responsible for control *(managers)* and those representing the community *(government)*. This lack of collaboration has a negative impact on the coordination of healthcare initiatives. Mintzberg *(2002)* concludes that there are "disconnections at every level, especially between clinical operations and management" *(p. 204)*. Mintzberg also admits that the study of healthcare does not involve nursing and other functions within the healthcare environment with the implication that the addition of these functions would have further exacerbated the disconnection.

Mintzberg *(1989)* found that healthcare organizational characteristics affect the implementation of technological innovations due to their professional bureaucracy and institutionalism. In these organizations, decision making is carried out by specialists from different professional backgrounds. Each medical service defines their own strategies based on their primary objective without taking into account the administrative impacts of their decisions and the needs of the others services. According to Mintzberg, several researchers have identified organizational characteristics that play a significant role in the implementation of ICT, such as the work organization, decision-making, communication modes, change management, financial incentives, collaboration between health units and affiliations *(Hikmet et al., 2008; Carpenter et al., 2011)*.

1.2 Technological investments

The total spent on ICT in the hospital market in 2006 was estimated to be between US$11.6 and US$12.8 billion, while the possible savings estimated from ICT implementation in the hospital environment is over US$77 billion per year *(O'Dell, 2006)*. Haughton *(2000)* stated that information is a source for improved delivery of health services and increased efficient and accurate decision making. In addition to patient safety, other benefits expected from implementation of ICT systems include support of the patient care function and facility administrative and operative activities *(Flower, 2006)*.

Langabeer *(2007)* has developed a model with three phases to explain the technological maturity of the healthcare organizations. According to this author, most of the healthcare institutions are in Phase 1. In this phase, the healthcare and administrative processes are manually performed and most of them are documented in paper. Technological innovations are poorly presented in this phase. Two reasons may explain this situation *(Jha, 2010)*. The first, technical issues, refers to the lack of interoperability between systems available in the market, which limits the ability to share data between organizations. Second, administrative and financial issues refer to the cost of the technological systems, their maintenance and updating and staff training.

An institution moves to phase 2 when it replaces some critical manual processes with high intensity intelligent systems, for example it uses ICT for procurement, planning and inventory control activities. Finally, an institution reaches phase 3 when all the processes and transactions between the institution, its suppliers and each care unit are automated. In this phase, technological innovations are used for the execution of healthcare services, for supporting decision making and for executing administrative processes.

According to the Langabeer model, inter-organizational information systems *(IOIS)* enable to automate care and administrative processes for phase 2 and 3. IOIS supports organizations' cross-border processes. It could drive coupled processes between two entities or more. IOIS improves the quality of the information flow by reducing or eliminating errors, compresses cycle time in the fulfilment of business transactions regardless of geographical distance, eliminates paper processing and its associated inefficiencies and costs and makes the transfer and processing of information easy for users. Electronic Data Interchange EDI, Radio Frequency Identification RFID and Computerized Patient Order Entry CPOE used for medicines and medical supplies procurement are some examples of IOIS. An IOIS system can be adopted in two different patterns by adopting a closed-loop or open-loop implementation strategy. A closed-loop implementation concentrates the adoption and use of the system into a well-defined entity, meanwhile, an open-loop strategy triggers the implementation and use of the system by two or more organizations.

1.3 Managing technology implementation projects

The science of project management is relatively young in the healthcare industry *(Bernstein at al., 2007)*. Nevertheless, within the fiscal restraints, medical errors, and a growing and better informed population, healthcare organizations have started to focus on the value of incorporating project management principles in their management practices. Several authors consider that healthcare projects are unique and more complex because of the products and services they are meant to provide *(Bernstein et al., 2007; Lisa Anne Bove, 2007)*. Project managers must deal with monetary, quality and time pressures from internal stakeholders *(sponsor, healthcare professionals, administrative staff and patients)* and from external stakeholders *(government, providers, general population, and medical associations, among others)*. This complexity could explain why ICT projects could easily fail.

In this context, the ability to successfully deliver projects is considered a competitive advantage *(Söderlund, 2005)*. This requirement is also requested by regulatory institutions which place additional burdens on the healthcare sector. For instance, the Health Insurance Portability and Accountability Act *(HIPAA)* establishes additional project management controls and requirement in order to ensure the successful implementation of ICT in healthcare and gain a profitable return of investment *(Bernstein et al., 2007)*. Regulatory institutions look for ways to avoid project failures that could impact negatively the economic stability of the sector. For instance, the Healthcare Corporation of America HCA decided to cancel in 2003 its Millennium Accounts Receivable System *(MARS)* due to project management failures. This cancellation accounted for an estimated US$110 to $130 million loss for HCA *(Nashville Business Journal, 2003)*.

To ensure successful ICT healthcare implementation, project managers must integrate two different principles to their practices. The first, the professional logic, considers the importance of professional and technical groups in the definition of requirements and in the validation of the final solution. These people are more able to better define the specific problems and can accelerate the acceptability and appropriation of the delivered product or service. This logic is also justified by the fact that the hospitals operate in a professional bureaucracy that maintains and promotes the development of several professional subcultures *(physicians, nurses, administrators, engineers, technicians, etc.)*. The second principle, the project logic, considers the value of fostering links of cooperation and exchange between professionals and of sensitizing stakeholders on the importance of submitting their requirements and their deliverables in terms of time, cost and quality *(project management trilogy)*. The integration of these two principles triggers the use of robust methods for project management, as well as a clear initial agreement among stakeholders on what is meant by success, and determining how it will be measured *(Nervegna et al., 2010)*.

Another complication to successful implementation of ICT in the healthcare sector is the need to address the relative power over the adoption or resistance to the new technology. Kaplan and Harris-Salamone *(2009)* suggested that ICT project managers must evaluate the technological dynamics on work procedures and on the relationships between clinical and administrative staff. People affected by the integration of ICT are involved in a process of learning and experimentation in which they could accept or reject the technology innovation *(Bertoluci et al., 2013)*. Consequently, technology implementation projects must be understood as a system where organizational change is the cornerstone. Considering only the technological characteristics by assessing the organizational perspective could result in failure. To integrate both perspectives, Kaplan and Harris-Salamone *(2009)* suggest entrusting project management responsibility to multi-disciplinary teams, experts with technological, clinical and administrative backgrounds.

Karlsen and Gottschalk *(2004)* pointed to another problem facing ICT project success: the inability of the project managers to thoroughly transfer knowledge between different health services units and ICT groups involved in the project. The adoption of new technologies requires an attitude of research and self-training in order to learn about the products and processes to be implemented. "Effective knowledge management reduces errors, creates less work, provides more independence in time and space for knowledge workers, generates fewer questions, produces better decisions, reinvents fewer wheels, advances customer relations, improves service, and develops profitability" *(Karlsen & Gottschalk, 2004, p. 4)*.

Bernstein et al. *(2007)* focused on the role of final users in project management. They pointed that the key to successful implementation of ICT in healthcare requires involvement of the end user*(s)*. He concluded that "users are less likely to use technology if there is no direct visible benefit to them in the performance of their job" *(p. 22)*. Project managers must focus on communicating benefits and consider the final users' position in order to ensure their involvement. Garcia and Turner *(2006)* explored the impact of user likeness to new technologies. They concluded that successful projects are dependent on the maturity of the organization and users to accept and use technological innovations. They add that organizations that have experienced successful implementations are more likely to accept new technological projects.

2. Methodological strategy

From the above discussion, managing technology implementation projects in healthcare industry is complex and projects could easily fail. ICT innovations differ in nature and in application type. This is the case of IOIS that could be adopted either in an open-loop model or in a closed-loop implementation. Within the specific focus of this paper, several questions remain to be answered: Should project managers follow the same practices for different ICT applications? More specifically, which factors must be considered for implementing an ICT innovation in a closed-loop setting? Which ones must be assessed for implementing an ICT in an open-loop setting?

In order to develop an understanding of ICT adoption projects and differences between an open-loop and closed-loop implementation, a multiple case study was executed. The following sections describe the technology chosen in this study *(namely, RFID technology)*, the selected application *(track and trace system for medicines)*, the selected cases studies *(end-to end verification system versus two-bin system for medicines inventory)*, the data collection methods and, finally, the participants.

2.1 Technology: RFID

RFID technology is "one of the most promising and discussed auto-identification and data capture *(AIDC)* technologies" *(OECD, 2008)*. It is a wireless technology that facilitates the identification of products without requiring a line of sight *(Bendavid and Bourgault, 2008)*. There are three basic components for a RFID system: an antenna including reader, a middleware and a radio frequency tag electronically programmed with unique information. The antenna is responsible for emitting radio signals and transferring electri-

cal power to read and write data to the tag *(Castro and Wamba, 2007)*. The antenna is capable of maintaining a constant electromagnetic field to communicate with a large number of tags. The middleware interprets the data stored in the tag's integrated circuit, which is transmitted through the antenna, and passes it to the computer for processing. RFID tags are classified as passive, semi-active and active *(Wamba et al., 2007)*. Passive tags receive power through induction during the communication with the reader, while active tags are internally powered.

The primary advantage of RFID technology is its non-contact, non-line-of-sight communications abilities. It is distinguished from barcodes or other optical recognition technologies in that RFID tags can be read through adverse environments *(Romero and Lefebvre, 2013)*. Its wireless communications ability also allows a larger quantity of tags to be read in a relatively short period of time. A wide range of automated data collection and identification applications would not be possible without the high speed of RFID technology.

Many companies around the world are incorporating RFID into their products in order to make their supply chain and logistics operations more efficient. However, there are different types of systems used in different areas that are incompatible with each other. The health care system is interested in implementing RFID applications because of its identifying, tracing and tracking abilities *(Romero et al., 2011)*. The purpose of RFID implementation is to design safe and reliable applications to assure patient security and quality service. Main RFID applications in the health care sector are: i) medical stock control, ii) pharmaceutical and medical devices supply, iii) assets management and iv) patient and staff identification *(FDA, 2006)*.

RFID technology can be implemented in a "closed-loop" setting when it is used internally by a single organization, for example, in a medical asset identification and localisation system or in a patient identification system. On the other hand, it can also be implemented in an "open-loop" setting when several organisations are affected by the RFID system such as medicine or medical asset procurement and distribution system. For the healthcare entities, an open-loop implementation is also considered when more than one health service unit is involved. For instance, the adoption of RFID technology for medication administration to patients is implemented in an open-loop vision because the technology system affects processes in the hospital pharmacy unit and the primary care unit. In this situation, RFID clearly fits the definition of an inter-organizational system *(IOS)*.

2.2 Application: track and trace system of pharmaceuticals

Medication consumption has doubled worldwide over the last few years, from 135 billion *($ U.S.)* in 2001 to 320 billion *($ U.S.)* in 2011 *(IMS, 2012)* and is very likely to increase in the next years due to baby boomers in industrialized countries and more reliance on medicines in newly industrialized and developing countries. Medicines represent a critical component of healthcare but face a number of critical issues such as the growing presence of counterfeit medicines, the deep impact of medication errors and the adverse impacts on the environment *(Lefebvre and Romero, 2013)*. At the same time, medicine management faces some serious roadblocks, namely the very complexity of the pharmaceutical supply chain, the multi levels of medicine packaging, fragmented regulation and weak enforcement *(Lefebvre and Romero, 2013)*. These issues and roadblocks point to the necessity of ensuring the sustainability of health care systems while protecting medicine safety and the pharmaceutical supply chain integrity.

Track and trace systems could strengthen the integrity, availability and authenticity of medicines. Also known as traceability systems, they enable their identification at any point in the pharmaceutical supply chain or at any point of the hospital. They also allow controlling their flow and their related information throughout their life cycle. Track and trace systems have been addressed by pharmaceutical companies, governments, health care institutions and individuals. For instance, these organisation are implementing these systems to totally or partially resolve issues related to counterfeit drugs *(Potdar et al, 2006, Bobée , 2009)*, to the cold chain[1] *(Roach and Wunder, 2008)*, logistics costs *(Lin et al, 2010)* and medical errors *(FDA, 2006)*. For example, the identification and tracking of medicines during the administration of doses to the patient could reduce 50 % of medication errors *(FDA, 2006)*.

To ensure the operability of track and trace systems, medicines must be identified at the unit level throughout their life cycle. RFID technology enables this mass serialization of medicines. The RFID tags which can be attached to the medicine package could hold medicine information such as

1 The cold chain refers to the transportation of medicines sensitive to temperature changes throughout the supply chain. It also includes the planning of logistics processes necessary to protect these products.

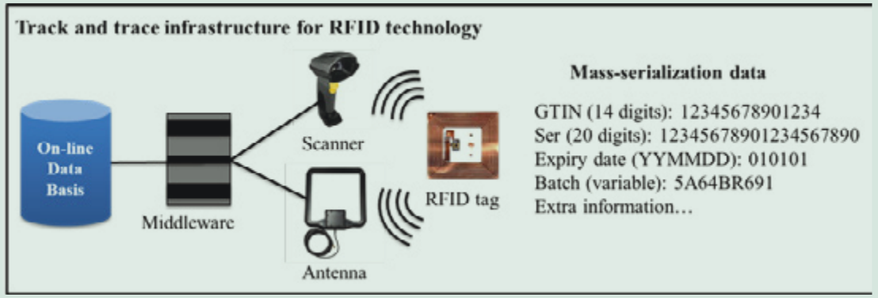

FIGURE 1. *Track and trace system based on RFID technology*

the product code, serial number, expiration date, batch code and transactional and commercial information *(Lefebvre et al., 2011. The identification at the unit level is respected because RFID tag has enough capacity to store a unit code by item (see right hand-side of figure 1)*. Information stocked by the RFID tag can be transmitted directly and without direct line of sight to a reader by radio frequency. The reader can then transfer the information to an enterprise information system for processing *(see left hand-side of figure 1)*. The EPC Global, the association responsible for developing and broadcasting RFID standards, has established a committee for developing a track and trace platform with anti-counterfeiting purposes *(Schuster, 2007)*. In 2007, this committee proposed an on-line data base containing information about the reception and transferring of medicines through each stage of the supply chain. The GS1 EPCglobal Electronic Pedigree Standard supplies the mass serialization capacity at item level using GTIN standard and the on-line transaction capacity using XML language *(Faber, 2008)*.

2.3 Cases studies

A multiple-case strategy "yields a more robust and generalized theory than single case" *(Carvalho, 2013, p. 45)*. This approach has been adopted in order to compare the project management during a closed-loop technology implementation versus an open-loop implementation.

Closed-loop implementation: a two-bin system for medicine inventory

A two-bin system, also known as Kanban system, permits to better control the inventory of the hospital pharmacy. Medicines with the same chemical composition are stored in two different bins, namely minimal stock and reserve stock. Both bins are tagged with a RFID tag containing the data related to the medicines stored into the bin *(manufacturer product code, batch number, expiration date, and medicines quantity)*. When the medicines in the minimal stock-bin have been used up, pharmacy clerks place an order to refill or replace the medicines needed by reading the RFID tag. Medicine information is updated in the pharmacy information system and procurement orders are sent to medicine providers. During the replenishment lead time, the reserve or remaining stock-bin has enough medicines to last until the new place order arrives *(see figure 2)*. This system allows real-time and accurate records which enable to improve the inventory visibility and the readiness of purchase orders while eliminating manual, high-cost and periodic reviews. More sophisticated RFID tags could be used in order to control storage conditions such as expiration dates, temperature and humidity. RFID tags could monitor any environmental condition and send alerts to the pharmacy information system when medicine integrity is affected. The implementation of this system involves only the hospital pharmacy. Actual processes are totally impacted by its adoption. Even if the two-bin system allows automated purchase orders, medicine providers are not affected by its integration. Therefore, this system is implemented into a closed-loop setting.

Open-loop implementation: End-to-end verification system

End-to-end verification system proposes to trace and track the medicines at two levels of the pharmaceutical supply chain, namely man-

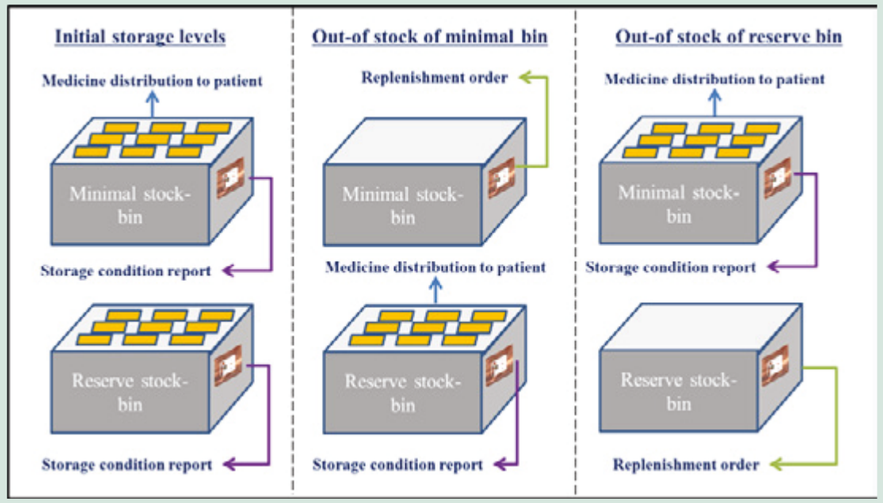

FIGURE 2. *Two bin system for inventory management: closed-loop implementation*

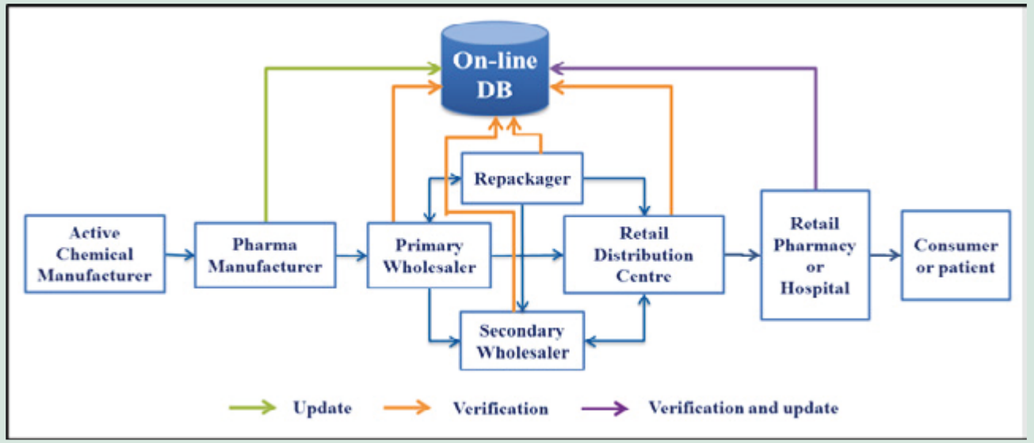

FIGURE 3. *End-to-end verification system: open-loop implementation*

ufacturer and point of sale *(i.e., hospital or retail pharmacy)*. Medicines are coded with a unique serialized number at unit level by manufacturers who record the product and its main characteristics *(manufacturer product code, batch number, expiration date, and serialization number)* in a central online data. The system therefore ensures that the product has been produced by a legal manufacturer and has been legally introduced into the pharmaceutical supply chain. Medicines are then distributed through the supply chain as usual to final retailer or hospital. Before selling the merchandise to the final customers or during medicine reception at hospital docks, medicine authenticity must be verified as follows: the pharmacists or hospital clerks connect to the central online data basis, read the RFID tag and compare the read data with the information registered by the manufacturer. They must validate that 1) "the product record exits and matches the data held on the product itself", 2) "the product record has not been previously marked as dispensed", and 3) "the product record does not contain any warnings or advisory notices" *(EFPIA, 2008)*. If the validation is correct, pharmacies must update medicine dispensation on the online data basis. The end-to-end verification permits to verify whether a pack with the same serial number has been dispensed before. Wholesalers, retailers and any other authorized organization can check this on-line data basis for security purposes; for example in the case of a suspicious event. Nevertheless, they do not have permission to update the existing data *(see figure 3) (Bobée, 2009)*. Thanks to the unique serial number at item level, this system could help to detect fraudulent products within the supply chain by knowing whether or not a product with the same serial number has already been dispensed. Moreover, it enables to fight against fraud reimbursement, avoid dispensing errors, facilitate detection of expired product and recall processes *(Bobée, 2009)*. The end-to-end verification system is adopted in an open-loop model because all the actors participating in the distribution of medicines are affected *(see* **Figure 3***)*.

2.4 Data collect methods

Field research was conducted over a period of two years. We relied on several sources of information, namely internal and external documentation, multiple on-site direct observations and semi-structured interviews. Both qualitative data *(for instance, comments from participants)* and quantitative data *(for example, the frequency of factual and documented events)* were collected. *Empirical data were analyzed using two main methods:*

Content analysis. This method, mainly used in qualitative research, allowed us to investigate the contents of project management communications, reports and data from interviews by classifying information objectively, and systematically *(Spanjers et al., 2005; Mackert and Whitten, 2009)*. This classification also enables quantitative analysis by controlling the frequency of thematic patterns and by exploring their relationship through inferential statistics. Content analysis was used to identify the main issues related to the RFID project management according to an open-loop or closed-loop implementation.

Processes mapping. This method represents a powerful tool to increase the understanding of complex organizational contexts and provides common ground to share and generate ideas *(Madison, 2005)*. As the large-scale implementations of technological systems generate deep changes to the implementing organisation, a process map analysis points to these changes, uncovers the main issues relating to this transformation and reveals best practices.

As noted by Paoletti and coauthors *(2007)*, the healthcare sector requires accurate and exact information in order to identify critical processes, recommend changes, and evaluate them with consistent and reliable data. Data and results from the field study were therefore triangulated and thoroughly validated through several iterative steps.

2.5 Participants

For the closed-loop implementation case *(two-bin system for medicine inventory)*, we have therefore concentrated our research efforts on a North American hospital with 400 beds, which represents the primary research site but we extended these efforts to five external organizations related to the management of medicines with the purpose of validating and triangulating the information obtained from the main research site. This hospital implemented this two-bin system supported with RFID technology in order to control the medicine inventory. A total of 20 people including project manager, caregivers, health professionals, technicians, managers, administrators and clerks participated in the field research, were systematically involved during observations and on-site interviews. The majority of these key participants *(12)* work in the main research site. In addition, 8 key respondents also provided valuable input and work, such as the medical technology director, quality and patient security director, chief pharmacist, president or project manager in five organizations, namely a government entity, two hospital centres, a pharmacy association and

Closed-loop implementation: two-bin system for medicine inventory		
Organisation	**Participants**	**Number of participants**
Hospital A (primary research site)	IT project manager	2
	Chief pharmacist	2
	Pharmacist	3
	Pharmacy clerk	3
	Material managers	2
Hospital B and C	IT project manager	3
Hospital association	Medical technology director	2
Pharmacist association	Association president	1
Technology consultant	Consultant	2
Total		**20**
Open-loop implementation: end-to-end verification system		
Organisation	**Participants**	**Number of participants**
Pharmaceutical association (EFPIA)	Project manager	2
	Manager	2
	Consultant	3
Manufacturer	Not apply	9
Wholesaler	Not apply	3
Distributor	Not apply	1
Pharmacy or Hospital	Not apply	3
Consultant	Not apply	7
Governmental institutions	Not apply	4
Total		34

TABLE 1. *Profile of Participants*

a technology provider. **Table 1** describes the participants in the field research.

For the open-loop implementation *(end-to-end verification system)*, we have executed our research within the European Federation of Pharmaceutical Industries and Associations EFPIA. This organization supports the implementation of the end-to-end verification systems. EFPIA has conducted several pilot projects in order to assess the functionality and the efficiency of this system. In September 2009, 14 manufacturers recorded 25 different medicines at the unit level. In total, 110,000 units have been distributed to 25 pharmacies in the greater Stockholm area *(Bonser, 2009)*. Preliminary results reflect that technology infrastructure is well adopted and the technological platform demonstrates an acceptable performance *(Bonser, 2009)*. In order to gain a better understanding of open-loop implementation, a total of 34 persons representing different organisations such as manufacturers, wholesalers, pharmacies, consultants and pharmaceutical associations were interviewed. Managers and project managers *(7 people)* from EFPIA were considered as the key participants of this research since they have a detailed vision of the end-to-end implementation project. **Table 1** describes the participants in the field research.

Factors for successful track and trace projects		**Closed-loop implementation**	**Open-loop implementation**
Technological	Expertise in technological characteristics and implementation	x	x
	Emphasis on technological benefits	x	x
	Compatibility with other technological investments	x	x
	Standardisation of technological solution		x
Organizational	Genuine stakeholder engagement	x	x
	Strong leadership for supporting project management decisions	x	x
	Coordination of investments		x
	Benefit-risk asymmetry		x
Project management	Use of an appropriate project management methodology	x	x
	Change management throughout all the project life cycle	x	x
	Mobilization and communication practices		x

TABLE 2. *Profile of Participants*

3. Results

Through a thorough content analysis of the comments and observations of the 54 key participants, we identified three groups of factors affecting the success of implementing track and trace systems, namely technological factors, organizational factors and project management factors. **Table 2** lists these factors according to two implementation modes: closed-loop and open-loop implementation.

Several participants described some technological, organizational and project management factors that affect both implementation settings: closed-loop and open-loop:

A deep expertise of RFID technology and its implementation contributes to the success of implementing track and trace solutions into a closed-loop and an open-loop setting. As pointed by several IT project managers, using RFID for identifying medicines requires an infrastructure with many components such as RFID tags, antennas, readers, middleware and system connections with other hospital information systems such as pharmacy information system PIS, computerized physician order entry CPOE, among others. The project manager and its team *(professionals from the pharmaceutical supply chain and the hospital)* must develop new competencies in order to implement this infrastructure and ensure its maintenance.

Several project managers and governmental advisors suggested that technological benefits must be easily identified by stakeholders in order to secure their engagement. Several actors from the supply chain and from the hospital were in full agreement with the performance of RFID technology. For example, some pharmacists stated: "in order to rely on RFID for medicines identification, the read rates must entail correct lectures during all the medication activities". Although RFID reading reliability has steadily increased over the last years, the overall perception in the healthcare organizations remains that current RFID systems still experience problems with reading accuracy. Even if these two factors *(emphasis on technological benefits and genuine stakeholder engagement)* are appropriate for both implementation modes, it seems to have critical importance for an open-loop implementation. In the case of the end-to-end verification system, actors supporting the system have different perceptions of RFID benefits, resulting in misunderstandings and in a poor stakeholder's involvement.

Compatibility could influence in the success of track and trace systems. Throughout the supply chain and inventory processes, medicine personnel use different types of equipment such as

barcode and/or RFID lectors, ERP, electronic prescribers, robots to dispense medication, among others. A track and trace system that is compatible with the actual technological solutions in the supply chain and the hospital pharmacy should be easily implemented. One IT project manager concludes, 'if RFID is not compatible with existing equipment, the cost of implementing the new infrastructure will increase drastically and the hospital will postpone RFID use". A closed-loop implementation and an opened-loop implementation are both affected by this factor, but because of different actors involved in the opened-loop system *(manufacturers, distributors, retail pharmacies and hospitals)*, it is difficult to achieve full compatibility.

Two factors related to project management practices could influence the success of implementing track and trace solutions. According to a healthcare advisor, "project management within integrated healthcare initiatives do not require improvisation". Participants in this research agreed that healthcare technology projects are complex because of the inherent healthcare context: financial pressures, medical errors, total quality, among others. Therefore, a proven project management methodology could guide project managers' decisions. However, according to several participants, there is no appropriate methodology that could be used in the context either for a track and trace solution or RFID technology in healthcare. Some other participants suggested that this implementation guide should be supported with performance indicators not only for having a complete planning model but also for controlling the project efficiency. The second project management factor influencing both implementation modes is the integration of change management practices throughout the entire project life cycle. The implementation of a new technological system such as a tack and trace system introduces changes into the existing processes that may impact "stakeholders' roles, rules, procedures, structures and communication, and their interactions with the external context" *(Papadopoulos and Merali, 2009, p. 3)*. This could result in organizational resistance to change that hampers the success of projects. As stated by one pharmacist, "two elements are essential to ensure the utilization of RFID technology for identifying medicines: it must be simple to use and be transparent for the patient." Therefore, project managers from both case studies suggested that change management must be introduced at the beginning of the project definition.

We identified four more factors *(one technological, two organizational and one related to the project management)* that only influence the success of implementing track and trace system in an open-loop setting:

The standardization of the technological solution and coordination of organizational investments only affect the implementation of RFID technology in an open-loop pattern. Some regulatory advisors explained that "the end-to-end verification system is supported by several actors who are developing their home-made solutions to identify medicines. Some of them use barcode, while the others use RFID technology". It seems that the different technological configurations and different organizational investments could hamper the implementation of a unique track and trace system. This factor gains more importance when government and pharmaceutical industry looks for ways to implement a track and trace system into a same country or a geographical region *(i.e., End-to-end verification system for the European region)*.

Open-loop implementation is considered to be more complex than the closed-loop one because it requires the coordination and cooperation of various stakeholders. In the case of a track and trace system for medicines, actors perceive the implementation projects differently. Some of them *(such as manufactures, pharmacy retailer and hospital)* must invest in technological infrastructure as well as new competencies to ensure the appropriate operability of the system. According to several participants, manufacturers are those who are more involved with the implementation but are those who receive more limited benefits. Meanwhile, the other actors *(such as distributors, wholesalers, repackages)*, less affected by the technology implementation, gain more interesting benefits, such as a better inventory control and logistics process improvements. This dynamic, known as benefit-risk asymmetry, could delay the implementation of the track and trace solutions.

Mobilisation and communication practices are considered by several participants as a solution for the benefit-risk asymmetry problem. RFID appears to be considered by the stakeholders as another technology push or as another wave of ICTs. If most IT project managers are committed to RFID adoption, the core mission of the pharmaceutical supply chain is still to provide medicines to the consumers and patients. Convincing pharmaceutical administrators and healthcare professionals that track and trace solutions would entail significant benefits to medicines management represents a critical and necessary step. Top management support, leadership, communication between different stakeholders, and training are also required to build the necessary level of organizational mobilization.

4. Conclusions

This paper assesses factors that could influence the success of ICT projects according to two different implementation modes: open-loop and closed-loop. Several participants pointed out the importance to assess technological, organizational and project management factors that affect both implementation patterns: expertise in technological characteristics and implementation, genuine stakeholder engagement, use of an appropriate project management methodology and change management throughout the entire project life cycle. Some other factors affecting both models but having a deep impact on the opened-loop implementation are: emphasis on technological benefits, compatibility with other technological investments and strong leadership for supporting project management decisions. Finally, we identified factors that only hamper the open-loop implementation: standardisation of technological solution, coordination of investments, risk-benefits asymmetry and mobilisation and communication practices.

According to these results, implementing the track and trace system in an open-loop setting is more complex than the closed-loop strategy. The open-loop implementation involves the coordination and collaboration of several actors which have different responsibilities, different competencies, different needs and different technological approaches. Coordination and engagement of stakeholders are critical requirements for adopting medicines traceability. This conclusion agrees with the OCDE statement about the adoption of ICT technologies in healthcare industry. According to this organization, the slow adoption of ICT technologies is due to the limited cooperation among the stakeholders and the absence of implementation methodologies *(OCDE, 2010)*. It seems that actual project management practices do not correspond to the healthcare context and to the track and trace implementing requirements. Therefore, research and managerial efforts must be undertaken in order to guide ICT implementation in healthcare.

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