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Map of risks for the implementation of radio-frequency identification: application of ancillaries in the university hospital Jean Verdier

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Ancillaries are surgical instruments, such as orthopedical instruments set for reconstruction of knee (a mounting arm...) used to implant or extract prosthesis. Their management involves the departments of sterilization and surgery as well as the suppliers. Such a long circuit exposes the instruments to potential risk hazards like a lack of traceability as the suspicion of Creutzfeldt-Jakob. In order to reduce the risk of errors we will propose the implementation of radio-frequency identification (RFID) to trace the ancillaries during each step of the supply chain. The objective of our study is to analyze and to map the risks associated with RFID implementation. A preliminary analysis of risks (APR) is conducted to map out the hazards for the implementation of RFID. The APR identifies 162 scenarios with a maximum risk connected to environment and technology. To reduce the risks identified, 22 courses of action are proposed, such as audits, training, and internal controls. For each action, a procedure has been designed and evaluated. This preliminary analysis of risks allows targeting the potential dangers for the RFID implementation applied to ancillaries and reduces them significantly.

1. Introduction

Ancillaries are devices in set (mounting arm, aiming block, locking handle...) provided by external manufacturers which are used to help surgeons implant or extract prosthesis (such a reconstruction of knee). They are lent for each surgical operation and their management is the same as that of other hospital supplies involving the departments of sterilization and surgery as well as the suppliers. Each ancillary is specific and may not share its characteristics with other ancillaries. To one specific surgery act correspond a specific ancillary. The hospital must be able to justify all actions related with ancillaries to the suppliers and if necessary to the patients. Each action of the ancillaries' handling must be traced from sterilization to the surgery block. Nowadays, traceability varies considerably from one hospital to another. In most cases the process is manual and incomplete. The solution lies in successfully implementing software that is easy to use and Radio-frequency identification (RFID) could provide an answer to this problem. RFID technology is just starting to get known in healthcare (Dinh 2008). It attaches radio-frequency tags to people or objects to provide identification, tracking, security, and other functions that fall under the general heading of automatic identification and data capture (Alberganti 2007). In healthcare, basic RFID is already being used to track patients for *anti-elopement* and *anti-abduction* programs. As more sophisticated systems move into hospitals, RFID is also beginning to be used to provide more extensive patient identification than traditional bar coding, and to track and locate capital equipment within the hospital.

In the near future, RFID could be used for a variety of applications, including tracking and matching ancillaries. RFID may ultimately be used for many of the functions currently carried

out by bar coding-but this will only be possible if the cost of RFID comes down.

Most of medical accidents which involve patients are caused by misidentification of medical items. This type of accident can be reduced, if the information about them - such as ancillaries - is managed automatically (Alberganti 2008). A RFID (Radio-frequency identification) tag can be identified automatically, since it uses wireless communication for identification.

In this study, the risks of implementing RFID to track ancillaries are evaluated by means of a functional analysis which allows the identification of hazardous situations and the scenarios of potential adverse effects. This analysis is conducted in order to establish how risks can be reduced and to set up a course of action to manage residual risk.

2. Investigations and results

2.1. APR system

The ancillaries' management in the Jean Verdier hospital was composed of six functions: reception of the ancillary from the supplier (such as orthopedic instrument set from Innomed manufacturer) (S1), sterilization of the ancillary (S2), send the ancillary to the surgery block with its traceability (S3), reception of the ancillary in the surgeon block with its traceability (B1), use of the ancillary in the surgery block (B2), and returning of the ancillary to the sterilization (B3). Each phase is conformed of three sub-phases (Table 1). Hazardous situations are also listed in Table 2. Based on these elements and the related hazard risks, the map of hazardous situations is drawn, using a score for each situation (Table 3), score 1 corresponding to a major risk and

Table 1: Functions and under functions of APR system

Functions	Sub functions		
Receive the ancillary from the supplier (S1)	Identify the ancillary	Validate the information	Send the ancillary to the block
Sterilize the ancillary (S2)	Wash the ancillary	Package the ancillary	Sterilize the ancillary
Send the ancillary to the surgery block (S3)	Identify the ancillary	Validate the information	Return to the supplier
Receive the ancillary from sterilization (B1)	Identify the ancillary	Store the ancillary	Validate the storage
Use the ancillary in the surgery block (B2)	Identify the ancillary with the prosthesis and the patient	Put on the prosthesis with ancillary	Disinfect the ancillary
Return the ancillary in the sterilization (B3)	Identify the ancillary	Return the ancillary to sterilization	Validate the storage

Table 2: List of potential hazardous situations

Generic hazards	Specific hazards	Hazardous situations
Operational (OPE)	Operation	Bad organization causing a loss of traceability Insufficient and not updated competence Interpersonal conflicts
Environmental (ENV)	Hostile conditions	Alteration of the chip by water Extreme conditions of pressure High temperature Alteration of the chip by chemicals
Technical (TEC)	Technology and computing	Interference with waves radio Breakdown of computer network No interoperability between the various computing supports Absence of competition of the suppliers Collision during the reading or the writing on the chip Hacking of information
Legal (LEG)	Regulations	Disregard of the requirements of the health government Disregard of the privacy rights of patient Disregard of the ISO 18000 standard Disregard of the CE branding Disregard of the convention between supplier and hospital Disregard of the ATNC norms

score 2 to a minor risk. Seventy six (65%) score 1 hazardous situations were identified and 40 score 2. Only the score 1 hazardous situations will be treated in priority to assure a secure management of ancillaries.

2.2. APR scenario

In order to evaluate each hazardous situation, severity, credibility, effort, and acceptance of risk scales were outlined (Table 4). The severity is composed of 5 levels ranging from G1 to G5, G1 representing a minor effect and G5 a catastrophic one. The

credibility is defined by the team and determines the probability of future hazardous situations. The acceptance is composed of 3 levels ranging from C1 to C3, C1 representing an acceptable risk and C3 an unacceptable risk. The effort scale is composed of 4 levels ranging from E0 to E3, E0 representing zero effort to reduce the initial risks and E3 a large effort.

For each scenario, the cause of the potential hazardous situation is evaluated according to the consequences it may have and using the scales described above. The APR scenario is shown as a table comprising 162 scenarios which allows a graphical representation using Kiviat diagrams (Fig.). The Kiviat diagram

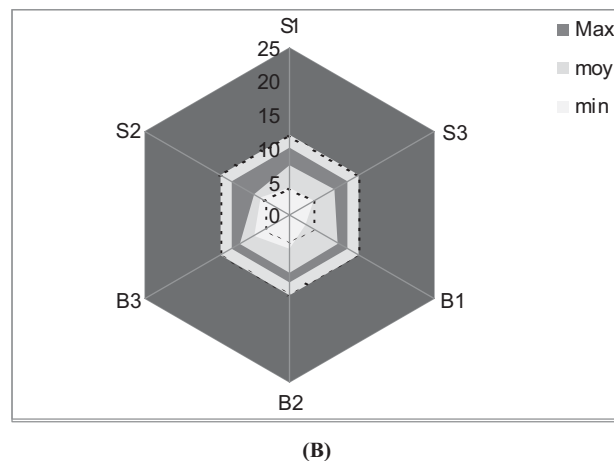
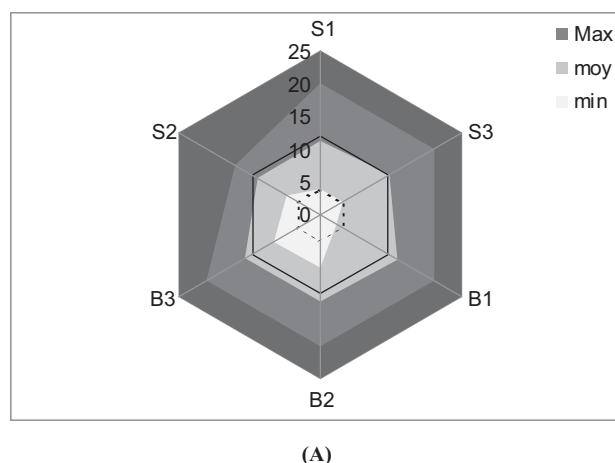


Fig.: Kiviat diagrams of the initial risks (A) and after the plan of reduction risks (B)

Table 3: Map of hazardous situations

		Receive the ancillary from supplier (S1)			Sterilize the ancillary (S2)			Send the ancillary (S3)			Receive the ancillary from the sterilization (B1)			Use the ancillary into the surgery block (B2)			Return the ancillary to the sterilization (B3)		
		Identify the ancillary	Validate the information	Send the ancillary to the surgery block	Wash the ancillary	Prepare the ancillary	Sterilize the ancillary	Identify the ancillary	Verify the information	Return the ancillary to supplier	Identify the ancillary	Store the ancillary	Validate the storage	Identify the ancillary with the patient	Put on the implant with the ancillary	Decontaminate the ancillary	Identify the ancillary	Send the ancillary to the sterilization	Validate the storage
Operational	Bad organization causing a loss of traceability	1		2	2	2	2	1	2		1	2	1	1	2	2	1	2	1
	Insufficient and not updated competence	1						1			1		1	1			1		1
	Interpersonal conflicts	2	1	2	2	2	2	2	1	2	2		1	2	2	2	2	2	1
Hostile Conditions	Alteration of the chip by water				1											1			1
	Extreme conditions of pressure						1												
	High temperature				1														
	Alteration of the chip by chemicals				1											1			
	Interference with waves radio	1						1		1		1	1				1		1
Technological and computing	Breakdown of computer network	1	2					1		1		1	1		2	1	2	1	
	No interoperability between the various computing supports	1	2	2	2	2		1		1		1	1				1		1
	Absence of competition from suppliers	1	2					1		1		1	1				1		1
	Collision during the reading or the writing on the chip	1			1			1		1	2	1	1				1	2	1
	Hacking of information	1						1		1		1	1				1		1
Legal	Disregard of the requirements of the department of health				1														
	Disregard of the privacy rights of patient		1					1						1					
	Disregard of the ISO 18000 standard	2	2					2	2		2			2			2		2
	Disregard of the CE branding		1	1										1					
	Disregard of the convention between supplier and hospital		1																
	Disregard of the ATNC norms		1											1					

of initial risks shows that the maximum risk dispersion has an impact on most of the system, while the medium risk dispersion diagram has an impact on the circuit of the ancillary in the surgery block. After the plan of risk reduction (Fig.), the potential hazardous situations are controlled, scoring C2 on the cruciality scale (acceptable and under control). For the minimum risk, functions B2, B3 and S2 score C2 on the cruciality scale. Following the plan of risk reduction, scale C2 changes to score C1 (acceptable).

2.3. Plan of risk reduction

Hazardous situations resulting from the APR scenario which scored C3 in the cruciality scale are listed and a plan of risks reduction is elaborated. This plan comprises 22 actions divided in 6 categories such as: audit (1 action), continuous controls (10 actions), training plans (3 actions), management (3 actions), mediation (1 action), and system of information (4 actions). A plan is established for each action, and determines a specific period for each, according to the effort needed to obtain the objective of a residual risk. The period ranges from immediate delay to 9 months delay. Immediate delay corresponds to the largest effort. For each action, a procedure is established which specifies the target scenario, who is responsible, the description of the action, the objectives, validation and controls of the action, and the rate of the residual risks. For example, a plan is established for reduce the hacking of information which

is estimated at an unacceptable hazardous situation. The specific procedure establishes the implementation of a complete secure information network by the computing department without delay.

3. Discussion

Hospitals are confronted daily with various difficulties while manufacturing, storing, transporting, and distributing products such as ancillaries. The establishments have to deal increasingly with the patients' complaints in case of disputes. As a result, it is not surprising that hospitals consider the implementation of radio frequency identification, RFID, as an answer to these problems, as well as a means of reducing costs. An instructive report by Aberdeen Research published in 2007 indicates that 38% of the companies using RFID do so in order to reduce the costs, the security and the reliability in their manufacturing process. In the field of health, RFID allows products such as ancillaries to be traced in their circuit. The principle is always the same: to identify an object and follow its path from place to place. RFID makes it possible to follow an object without having to manipulate it and guaranteeing that its path will be traceable and free of any intervention or interruption, in a completely automated way. At any time during the life of an ancillary equipped with an RFID label, it is possible to read the information contained in the memory of the chip. As a result, the sterilization block, the surgical unit, the finance department,

Table 4: Severity, credibility, effort, and acceptance of risk

Severity	Index	Repercussions	Credibility	Effort	Acceptance
G1 (minor)	11	No impact on the performances and security	V1 (impossible)	E0 (no effort)	C1 (acceptable)
		Unavailability of the ancillary without clinical impact	V2 (not very likely)	E1 (weak)	C2 (under control)
	12	Unavailability of the ancillary without change in care	V3 (unlikely)	E2 (medium)	C3 (unacceptable)
	13	Patient not satisfied	V4 (likely)	E3 (important)	
	14	Technology not controlled without change in care	V5 (very likely)		
G2 (significant)	Degradation of the performances without impact on security				
	21	Unavailability of the ancillary without moderate clinical impact			
	22	Unavailability of the ancillary causing a therapeutic adjustment or a change in care			
	23	Alteration of the hospital image			
	24	Technology not controlled with change in care without prolonging the average duration of stay			
	25	Resistance in changes			
	Failure of the performances of the system without impact on the security				
	31	Unavailability of the ancillary causing a therapeutic adjustment or a change in care with prolonging the average duration of stay			
G3 (serious)	32	Judicial procedure			
	33	Important clinical consequences			
	34	technology not controlled causing a therapeutic adjustment or a change in care with prolonging the average duration of stay			
	35	Staff on strike			
	Degradation of the security or the system integrity				
	41	Unavailability of the ancillary for surgery			
G4 (critical)	42	Imitation of the ancillary without consequence for the hospital			
	43	Judiciary procedure			
	44	Hacking of information without consequence for the hospital			
	45	Breach of contract between the supplier and the hospital			
	Failure of the security or the system				
G5 (disastrous)	51	Breach of contract with consequences for the credibility of the hospital			
	52	Death of patient			
	53	Hacking of information with consequence for the hospital			
	54	No traceability			
	55	Imitation of the ancillary with consequence for the hospital			

or the supplier can be informed whether ancillaries (which are the responsibility of the Department of Health) are being repaired or loaned at any given moment.

The preliminary analysis of the risks for the implementation of a solution based on the radio frequency identification applied to ancillaries at the hospital, bases here on one the functional analysis, cartography of the dangers, cartography of the dangerous situations, the preliminary analysis scenarios and cartography of the risks. The map of hazardous situations includes 116 situations. The situations with a high hazard score (65%) demonstrate that in order to succeed in implementing the RFID solution in a health system, the risk analysis is very important. These dangers corresponded to technical (30%) and to operational (16%) situations. In an APR scenario, the more hazardous situations are categories S1, S3, B1, B2 and B3. In category S2, the situations are less hazardous given the processes are controlled in sterilization. The Kiviat diagram shows the environment impacts

strongly on the implementation of the RFID solution to track the ancillaries and that less for the technical. For the operational and legal hazards, the average risk is acceptable and under control. The plan of risks reduction implies a majority of actions which characterize a very important effort before implementation of RFID solution.

4. Experimental

To determine the potential risks for the implementation of RFID to track ancillaries in a hospital, a work group was formed comprising representatives from the following departments: sterilization, risk management, surgery, finance and nursing.

4.1. Selection of workgroup

The members of the committee were selected by the risk manager (first team leader) and the sterilization manager (second team leader) at the origin of

the project. For example, in the surgery department, the surgeon and the nurse were selected by their great experience in ancillaries. In the finance department, the choice has door on the person who managed the ancillary's orders. All selected members have read and signed the project documents. Every week the workgroup met and changed their experiences in function of the advanced results. When all members were agree with the elements of the constitutive map of risks, the risk manager compiled the results to elaborate the preliminary risk analysis.

4.2. Preliminary risk analysis

The preliminary risk analysis (APR) is based on the preliminary hazard analysis (PHA). PHA is a semi-quantitative analysis that is performed to identify all potential hazards and accidental events that may lead to an accident, rank the identified accidental events according to their severity and identify required hazard controls and follow-up actions (Hyatt 2003; Reason 2004; Nolan 2008). As the PHA, the APR shall consider hazardous components, safety related interfaces between various system elements including software, environmental constraints, operating and emergency procedures, and safety related equipment, malfunctions to the system.

To be able to identify all hazards and events, it is necessary to split the system into manageable parts, for example, into three categories as process units, activities, exposed to risk. All hazards and possible accidental events must be identified. It is important to consider all parts of the system as operational modes. All findings are recorded. No hazards are too insignificant to be recorded. To get a complete survey of all possible hazards, a checklist is constructed and validated by the workgroup.

The APR is carried out in two stages: the APR system and the APR scenarios.

4.3. APR system

The objectives of the APR system are the determination of the generic and specific dangers, and the map of the hazardous situations. Common sources of hazards are sources of stored energy in electrical, chemical or mechanical form, mechanical moving parts, material or system incompatibilities, radio frequencies interferences, material collisions, corrosive actions, deterioration in long-term use, human error in operating, software error.

4.4. APR scenario

An outline or map resulting from the analysis of scenarios corresponding to each dangerous situation is drawn. The risk related to a dangerous situation is a function of the frequency of the event and the severity of its potential consequences. So, each dangerous situation is associated with a severity scale, a credibility scale, an effort scale, and an acceptance of risk scale. The severity of an event may be classified into rather broad classes. The workgroup has defined the severity classes in five ranks as G1 (minor severity) to G5 (disastrous severity) (Table 4). The credibility has to be related to the severity of an average consequence of each dangerous situation. The workgroup has defined the credibility classes in five ranks as V1 (impossible) to V5 (very likely) (Table 4).

The risk is established as a combination of a given event with its severity. This will enable a ranking of the credibility and severity for dangers in a risk matrix.

Therefore the map determines the initial risks in the first place and secondly the residual risks. If the residual risks have not yet been controlled, then corrective measures are taken in order to minimize the hazards. For each dangerous situation, a potential event is related with its consequences and its level of risk (severity, credibility, acceptance). In function the level of acceptance of risk, a plan of risk reduction is adapted to this situation.

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