

Risk Management Approach for a Secure and Performant Integration of Automated Drug Dispensing Systems in Hospitals

Hind Bouami, Patrick Millot

Abstract—Medication dispensing system is a life-critical system whose failure may result in preventable adverse events leading to longer patient stays in hospitals or patient death. Automation has led to great improvements in life-critical systems as it increased safety, efficiency, and comfort. However, critical risks related to medical organization complexity and automated solutions integration can threaten drug dispensing security and performance. Knowledge about the system's complexity aspects and human machine parameters to control for automated equipment's security and performance will help operators to secure their automation process and to optimize their system's reliability. In this context, this study aims to document the operator's situation awareness about automation risks and parameters involved in automation security and performance. Our risk management approach has been deployed in the North Luxembourg hospital center's pharmacy, which is equipped with automated drug dispensing systems since 2009. With more than 4 million euros of gains generated, North Luxembourg hospital center's success story was enabled by the management commitment, pharmacy's involvement in the implementation and improvement of the automation project, and the close collaboration between the pharmacy and Sinteco's firm to implement the necessary innovation and organizational actions for automated solutions integration security and performance. An analysis of the actions implemented by the hospital and the parameters involved in automated equipment's integration security and performance has been made. The parameters to control for automated equipment's integration security and performance are human aspects (6.25%), technical aspects (50%), and human-machine interaction (43.75%). The implementation of an anthropocentric analysis system before automation would have prevented and optimized the control of risks related to automation.

Keywords—Automated drug delivery systems, hospitals, human-centered automated system, risk management.

I. INTRODUCTION

MEDICATION dispensing systems are a life-critical system whose failure may result in preventable adverse events [1] leading to longer patient stays in hospitals or patient death.

The automation of pharmacists' tasks that require repetitive motions, high concentration and reliable record keeping, increase medication dispensing process safety, reduce drug waste, and exempt agents from manual tasks that are time-

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consuming [2]. Therefore, automation has led to great improvements in life-critical systems such as the nuclear industry or medical sector, as it increased safety, efficiency and comfort [3]. However, complexity is a significant aspect of the medication dispensing system. In fact, a medication dispensing organization is characterized by the interconnection of two circuits, logistic and therapeutic ones; and by the intervention of various agent profiles.

Some errors may occur due to miscommunication, inadequate knowledge, interruptions, computer interface, or a lack of sufficient decision support. These errors are related to organizational and human factors, and can compromise automated systems security and performance [4]. "Automation can also increase the complexity of the operator's supervisory task in situations where the automation is failing" [5]. Therefore, sectors dealing with life-critical systems and integrating automated solutions in their complex organization have to develop safety cultures by implementing a risk management system. Risk management helps organizations to identify and control risks and malfunctions, in order to optimize their system's reliability and to ensure safety.

The challenge is to control both types of risks: those related to organization complexity and those related to automated solutions integration. Therefore, risk management methodology should integrate the characteristics of an anthropocentric and a systemic approach to control the organization complexity. Critical human-machine parameters should also be identified and managed to ensure automated solutions integration safety and performance.

Three studies have been conducted in Dijon, Lens and Nord Franche-Comté hospital centers that intend to implement automated drug delivery cabinets [2], [6], [13]. The deployment of our risk management approach revealed potential risks that can threaten automation security and performance.

Our study conducted in Dijon hospital center discusses the issues of human-centered automation design of the medication dispensing process [6]. A systemic and anthropocentric approach is proposed, based on a diagnosis according to the phases of the V-cycle and an analysis of malfunctions according to the risk factors of the Boy pyramid [8]. The proposed approach leads to identify risks related to the organization, the system, the task, the situation and the operator. The use of this approach in Dijon hospital center's pharmacy provided the necessary prerequisites and helped in controlling the hidden risks and costs the organization.

Our complementary studies in Lens hospital center [2] and Nord Franche-Comté hospital center [13] confirm that automation is an effective but non-self-sustaining leverage. Medication errors that cannot be controlled by automation are related to organizational factors. The use of our approach revealed tasks that are eligible for automation and those that need human agent intervention. Human operator teams must then be fully integrated into the process, using their capabilities to manage the unexpected, identify and control automation risks and malfunctions, in order to ensure automated solutions integration security and performance in the organization.

Previous studies have been conducted in hospital centers that have not implemented automated drug delivery cabinets yet [2], [6], [13]. These studies value the results obtained in the prevention phase of automation risk management. The objective in this paper is to explore automation risks and malfunctions identified in the recovery and consequences phases of automation risk management. Therefore, the proposed approach has been deployed in a hospital center equipped with an automated drug delivery cabinet for more than 11 years.

The study of North Luxembourg hospital center's pharmacy feedback will enable us to capitalize knowledge about automated drug dispensing benefits, issues, and automation risks and limitations throughout the automation process. The analysis of automation limitations will be conducted in the light of the principles of systemic human-centered automation approach.

The main objective of this approach is to help hospitals build Team-Situation Awareness about risks and malfunctions that can threaten automated drug delivery systems integration security and performance in a pharmacy's organization. In this paper, Luxembourg hospital center's pharmacy needs and automation goals are identified, and its automated equipment's requirements fulfilling are evaluated, the risks and malfunctions related to automated solutions integration are analyzed, the parameters to control for automated equipment's integration safety and performance are identified and reported, and the results of the work are discussed.

II. RISK MANAGEMENT IN LIFE-CRITICAL SYSTEMS

A. Life-Critical Systems

Life-critical systems are systems whose failure may result in injury, loss of life or serious environmental damage. Three main attributes that characterize life-critical systems are: safety, efficiency, and comfort.

Delivering the right dose of the right drug at the right time by the right route to the right patient is a critical process involving patient safety, and malfunctions can lead to patient health complications or death. Therefore, medication dispensing system is a life-critical system whose malfunctions and risks must be identified, analyzed and controlled to optimize its reliability and to develop its resilience.

"In socio-technical systems, the resilience is due to combined human technological, organizational factors and the

environmental influences, and particularly, the interdependencies and adaptive behaviors" [10]. Amalberti defines resilience as a total safety (St) composed by an imposed safety (Sr) and a managed safety (Sg), according to the following equation: $St = Sr + Sg$ [11]. Observed safety relies on errors avoidance based on norms and quality helped by technology, regulations establishment, resilience assimilated to management surprises and based on human expertise, and adaptive learning systems.

Risky situations should be identified in complex systems, so decisions could be made on how to control and prevent risks and malfunctions. Adaptive behaviors imply the study of auto-organizational processes, the learning processes and feedback, the knowledge capitalization and sharing of best practices [10].

A strategy for risk management should be settled to control and prevent risks and malfunctions in complex life-critical systems such as automated medication dispensing process, in order to develop the system's resilience. The risk management approach should integrate feedback, and knowledge capitalization and sharing, to enhance adaptive behaviors in hospitals.

B. Strategy for Risk Management

In a risky system, the human is usually seen as an unreliable factor [3].

One of the automation challenges is to define a level of automation that makes a proper balance between human and automated agents in order to ensure a flexibility required for high-risk systems so human agents can make well-documented decisions and guarantee its resilience. In order to secure such a complex human-machine system, a strategy is required for risk management.

The risk management of an automated system will help human agents determine the risks related to human organization and those related to the automated equipment. Operators can then define and implement actions to ensure an automated system's security and performance.

Risk management approach relies on three phases: prevention, recovery and consequences management. Risk-based design methodology identifies the hazards of the system, and continuously optimizes design decisions [12]. Each one of the phases requires the application of well-defined techniques.

Prevention phase is based on qualitative approach to identify the hazards and risky scenarios requiring safety measures. The supervision of the system (monitoring, maintenance) helps implementing barriers (norms, procedures) that control identified risks and hazards.

Recovery phase is based on the analysis of occurred fails in order to implement short-term corrective actions such as procedures, specific organizational actions, support system for events detection and analysis, etc. Quantitative analyses are then conducted to evaluate malfunctions and risks occurrence, determine the tolerability of the consequences, evaluate their criticality, and implement an action plan.

Consequences management phase considers enhanced and/

or alternative designs. Changes are introduced and further measures are implemented to reduce risks to a tolerable level. Documenting the process safety system generates essential information for security management strategy of the organization and for the documentation of agents' situation awareness about their system's complexity and risks.

III. HUMAN-CENTERED APPROACH FOR RISK MANAGEMENT EVALUATION IN AUTOMATED SYSTEM

In Fitt's approach, human agents have added-value in reasoning, and decision making [7], while machines are performant in repetitive tasks execution, multi-tasking and complex calculations execution. Human-machine system design and evaluation should consider humans' and machines' abilities to define their authority and control levels, for a successful dynamic balance between humans and machines [9].

Human agents should then be involved in the design process of automation. Therefore, our approach for risk management evaluation in automated system integrates human in the loop (Fig. 1), and it is based on the classical design V-Model, but adapted to human-machine systems [8]. This anthropocentric approach helps automated hospitals to evaluate their automation process security and performance according to the principles of the human-centered approach for automation risk management.

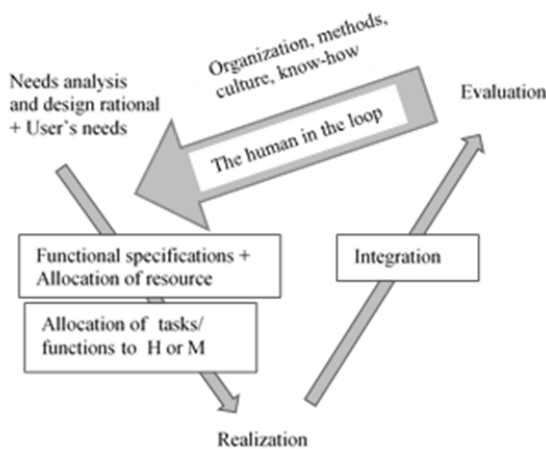


Fig. 1 V-Model adapted to Human Centered Design

Precisely, hospital operators Situation Awareness is documented by analyzing automation process risks and malfunctions identified by automated hospital pharmacies in the prevention, recovery and consequences management phases.

More specifically, the proposed approach documents medication dispensing system's functions and tasks, pharmacy's needs, automated solutions requirements formalized by the pharmacy to ensure drug delivery security and performance, risks and malfunctions identified during automated equipment's installation and use, critical parameters involved in automation limits, and parameters influencing Human Machine interaction and threatening

automated activity security and safety.

The proposed approach integrates six steps:

- 1) Identification of pharmacy's needs in terms of medication dispensing security and performance and their objectives,
- 2) Automated equipment requirements and functional specifications analysis,
- 3) Automation deployment results and related gains,
- 4) The evaluation of pharmacy's automated equipment requirements fulfilling and specific actions implemented to enhance automated activity security and performance,
- 5) Analysis of the parameters to control for automated equipment integration security and performance,
- 6) Analysis of factors influencing Human Machine interaction.

Human agents have to identify automation and system risks, and analyze their root causes. Operators then enhance their Situation Awareness from the modeling, the analysis and the reconfiguration of their system.

The objective of the proposed human-centered automation design approach is to evaluate automation goals achievement, and to document critical factors related to human-machine systems that were involved in risks, malfunctions and performance limits of automated drug delivery system.

The challenge is to identify and document operator's situation awareness about parameters influencing Human Machine interaction and performance in order to control them and prevent risks and malfunctions' occurrence. The methodology documents also the nature of the actions implemented to prevent or correct identified risks and malfunctions.

In high risk and complex systems, knowledge helps human agents understand a system's complexity fully, environmental factors that interact with the system, and the automation process; in order to avoid misunderstanding and mistrust of the system and automation.

As a medication dispensing system is a cross-organizational activity recognized as a complex high-risk system, it then seems convenient to apply an integrative human-centered automation approach. This approach enhances operator's situation awareness of medication dispensing systems risks and the role of automated and human agents in medication dispensing security and performance (Fig. 2).

The identification of the pharmacy's needs and objectives in terms of medication dispensing security and performance (step 1) and automated equipment's requirements and functional specifications analysis (step 2) enhance the operator's perception of the pharmacy's automation needs in the current situation. Automation deployment results and related gains (step 3) and the evaluation of the pharmacy's automated equipment's requirements fulfilling and specific actions implemented (step 4) help the comprehension of the current situation. The analysis of the parameters to control for the automated equipment's integration security and performance (step 5) and the analysis of factors influencing Human Machine interaction will help projection of future status of reorganized automated medication dispensing activity. Then operators build the decision-based reconfiguration of the

medication dispensing process with specific actions implemented in order to improve the automated equipment's integration security and performance.

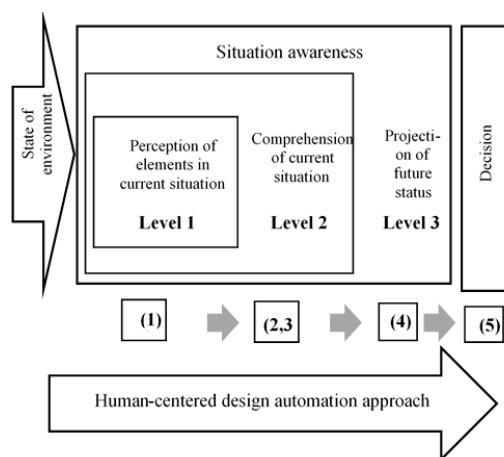


Fig. 2 Human centered automation approach adapted from Endsley's SA definition [14]

IV. CASE STUDY: FEEDBACK OF DRUG DELIVERY AUTOMATION AT NORTH LUXEMBOURG HOSPITAL CENTER

The objective of this study is to value North Luxembourg hospital center's feedback on drug delivery automation. The purpose is to explore risks and malfunctions related to automated drug delivery equipment's integration, and to identify the parameters to control in order to ensure automated activity security and performance. The retrospective risks analysis conducted in North Luxembourg hospital center will document agents' situation awareness on the risk management approach required for automated equipment's integration safety and performance in hospital medication circuit.

A. Diagnosed Establishment: North Luxembourg Hospital Center

North Luxembourg hospital center has 357 hospital beds including 275 in Ettelbruck and 82 beds in Wiltz. The objective was to meet the requirements of the regulation which recommends a drug unit-dose delivery in a perspective of security, efficiency and financial economy. The pharmacy's requirements for automated drug delivery are mainly to ensure the concordance between prepared treatments and the prescription, to distribute a maximum of galenic forms in their original or over-loaded packaging, to guarantee traceability of unit dose production at patient administration, and to be reliable and ensure controls at different levels of the process.

B. Drug Unit-Dose Delivery Automation Deployment

The North Luxembourg hospital center's pharmacy implemented Sinteco's automated drug delivery systems in 2009. The deployment of the project extends from 2009 to 2016. The evolution of drug unit-doses production performance is almost linear with a progression of approximately 50,000 drugs blisters production per year (Fig. 3). Also, the evolution of the number of unit doses distributed

is almost linear with an increase of approximately more than 100,000-unit doses distributed per year (Fig. 4).

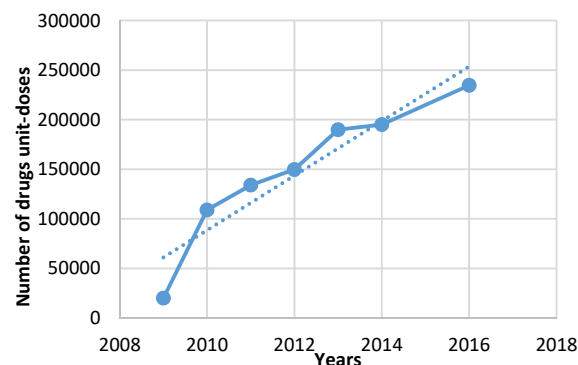


Fig. 3 Evolution of automated drug unit doses production

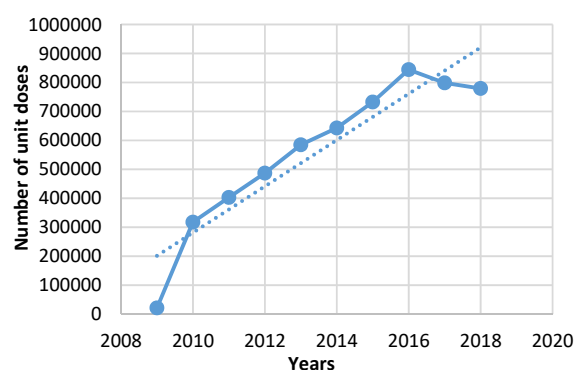


Fig. 4 Evolution of automated drug unit doses distribution capacity

The deployment of automated drug unit-dose dispensing has been gradual since 2009 in North Luxembourg hospital center. The hospital reached its target of 54.76% of automation production deployment across all beds in 2012, 71.73% in 2013, and 77.08% in 2014, and 100% in 2016. In 2017, the pharmacy documented the project of new equipment acquisition to bridge the gap between automated production and distribution of drug unit-doses, as the hospital's activity is continuously increasing.

C. Performance and Security Gains

As agents are freed from manual tasks eligible for automation, they are redeployed on high value tasks in the pharmacy which helps to prevent medication dispensing errors due to dosing errors, drug mix-up, and errors of omission. Also, North Luxembourg hospital center's automation feedback study highlights significant economic impacts: the annual cost of drug stocks decreased in care units, since the pharmacy prepares nominative drug unit-dose treatments. The pharmacy also reported an optimized management of drug expiry and returns. Furthermore, it appears that the acquisition of drug automated solutions avoided the recruitment of 4.28 full time-equivalent of pharmaceutical technicians, which would have been necessary for a manual nominative drug unit-dose delivery. So, based on their automation deployment performance, their achievement of the goal of dispensing

automated nominative unit-dose treatments for all patients, and the gains generated by the automation estimated to more than 4 million euros in 11 years, North Luxembourg hospital's automation experience is considered as a great success story of automation projects in hospitals. In fact, North Luxembourg hospital center achieved a return on investment in less than 11 years.

D. The Evaluation of Pharmacy's Automated Equipment's Requirements Fulfilling

North Luxembourg hospital center's pharmacy established the specifications of automated equipment needed to ensure drug dispensing activity security and performance. The pharmacy's needs fulfilling is evaluated (Fig. 5), and limitations and challenges faced by the pharmacy while implementing automated solutions are explored.

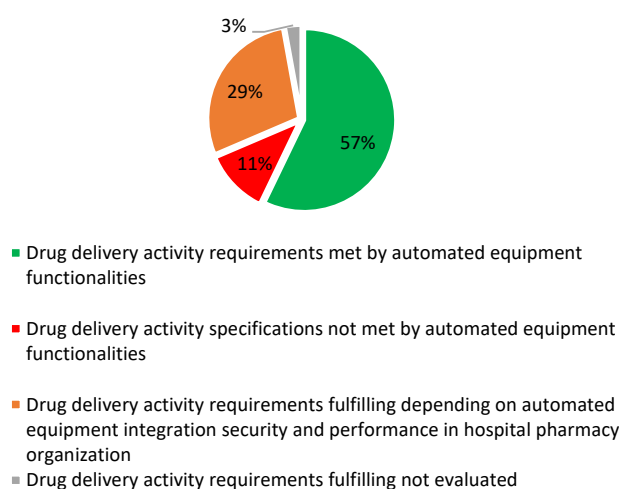


Fig. 5 The evaluation of drug delivery activity requirements fulfilling by automation

The study reveals that 57% of drug delivery activity requirements are met by automated equipment's functionalities such as delivering a maximum of galenic forms, managing different batch numbers of the same drug at the same time, ensuring traceability of unit dose production, reintegrating each return of medication into the stock of the automation, realizing an automated inventory at any time, etc. Most importantly, the speed of drug unit-dose production and treatment preparation are optimized and in good correlation with prescription changes and new entrants. Also, the continuity of work is ensured in the automation process. Additionally, the delivery of unit-doses bags to be administered does not get tangled in the clip and are not torn off during administration.

Only 11% of drug delivery activity specifications are not met by the automated equipment's functionalities: earplugs have been used by operators to protect themselves from the equipment's noise. Some 3% of specifications require verification by the pharmacy of their adequacy with automated solutions functionalities while, 29% of drug delivery activity

requirements fulfilling depends on organizational factors involved in the automated equipment's integration security and performance in the hospital pharmacy organization. For instance, the interfacing of DX-Care software installed in 2017 with the automated drug delivery systems resulted with some limits and malfunctions that the pharmacy had to deal with. Also, the integration of new technology is required sometimes so that the pharmacy could master the complexity related to the integration of automated solutions in human organization. So, by setting aside requirements depending on organizational factors, automated equipment met 84% of the pharmacy's requirements.

E. Automated Equipment's Integration Security and Performance

As seen previously, some drug delivery activity requirements are met by automated equipment functionalities but others rely on the security and the performance of the automated equipment's integration in the organization. The security and optimization of the automated equipment's integration in the organization required the implementation of specific actions (Fig. 6).

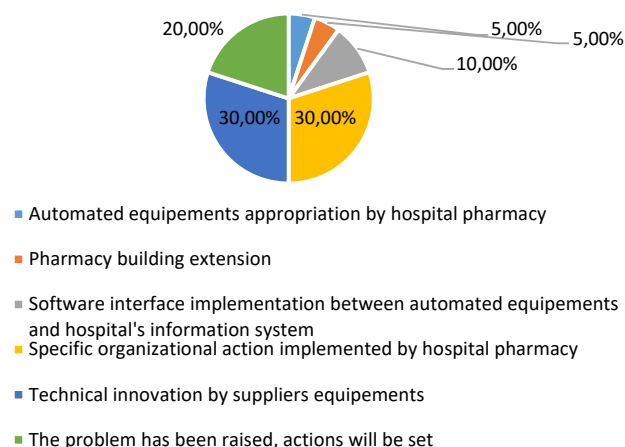


Fig. 6 Actions required for automated equipment's integration security and performance in hospital pharmacy's organization

The actions implemented by the pharmacy to secure and optimize the automated equipment's integration in the organization are:

- 30% of the actions are technical innovations implemented by the Sinteco's firm after the limits were shared by the pharmacy. In fact, the pharmacy reported to the equipment's development firm some optimization axes. The firm proceeded then to implement technical innovations such as extending the perimeter of the galenic forms provided by the automation, developing a new system without intermediate storage, optimization of drug unit doses production speed in new equipment, etc.
- 30% are specific organizational actions that have been implemented by the pharmacy, such as the computerization of batch traceability, the staff work with earplugs, the reorganization of the activity for

simultaneous production of drug unit-doses and drug doses to be administered, etc. Also, the expertise of a trained technician was necessary for the success of the project.

- 20% have no action actually but the problem has been raised and actions will be set,
- 10% are software interface actions,
- 5% are actions for the automated equipment's appropriation by the hospital pharmacy,
- 5% are actions of building extension.

F. Human-Machine System Parameters to Control for Automated Equipment's Integration Security and Performance

Identified human-machine system parameters to control are (Fig.7):

- 50% are technical aspects to settle which have required technical innovation implemented, or have no action actually but the problem has been raised for setting specific actions,
- 43.75% are human-machine interaction parameters which have involved organizational actions, software interface action, and pharmacy building extension,
- 6.25% are human aspects that required automated equipment's appropriation by hospital pharmacy and other organizational actions.

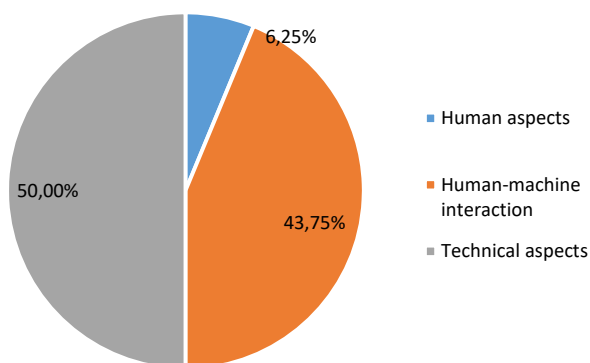


Fig. 7 Human-machine system parameters to control for equipment's integration security and performance

In the light of actions required for automated equipment's integration security and performance, it appears that technical, human, and human-machine parameters are needed for a safety an efficient automated solution implementation.

Sub-parameters to control for automated equipment's integration security and performance have been analyzed (Fig. 8):

- 31.25% are organization issues such as securing manual supplement to automated production, and optimizing drug storage in pharmacy,
- 25% are related to automated equipment's reliability such as pharmacy's decision of reducing automated production controls of final patient treatments content given the absence of production errors,
- 25% are related to tasks as scanning all drug unit-doses returned before being put back in stock,

- 12.50% are related to the interfacing complexity of DxCare software with hospital information system. Interfacing performance is related to the responsiveness of Dx Care software team to respond to hospital requests,
- 6.25% are cognitive as the mastery of automated new technology by the pharmacy.

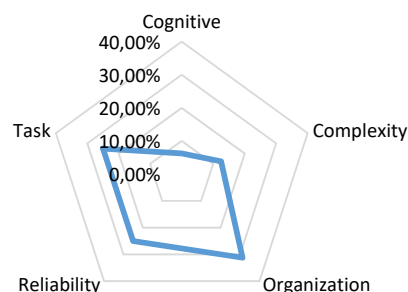


Fig. 8 Human-machine system sub-parameters to control for equipment's integration security and performance

Nearly half of the human-machine system parameters to control for automated equipment's integration security and performance are technical: the automated equipment's reliability, complexity, automated agents' tasks. The other half is related to human aspects and Human Machine interaction: cognitive, organization issues, human agents' tasks.

G. Factors Influencing Human Machine Interaction

The study revealed that some factors should be managed to secure Human Machine interaction (Fig. 9):

- 31.25% of the automation issues processed by the North Luxembourg hospital center's pharmacy require the understanding of the system's complexity,
- 31.25% need to define the relevant level of automation required,
- 12.50% need to determine solutions autonomy,
- 18.75% need to determine human agent's authority, and the authority given to automated solutions. By working with buffer stocks, operators have the authority to replenish automated drug delivery systems when needed. Given the fact that there was no error in production controls of final patient treatments, the pharmacy decides to trust equipment's reliability in automated process controls. So, they gave the authority to automated drug dispensing to manage unit-doses and patient treatments production from pharmaceutical validated prescriptions.
- 6.25% need understanding the human complexity.

V. DISCUSSION

Medication dispensing process is a complex human system that needs to apply an integrative human-centered automation approach that is confirmed by the parameters that appear to be involved in automated equipment's integration security and performance: human aspects, technical aspects, and human-machine interaction. Precisely, sub-parameters to be

controlled for automated solutions integration security and performance are: organization, task, complexity, cognitive, and reliability.

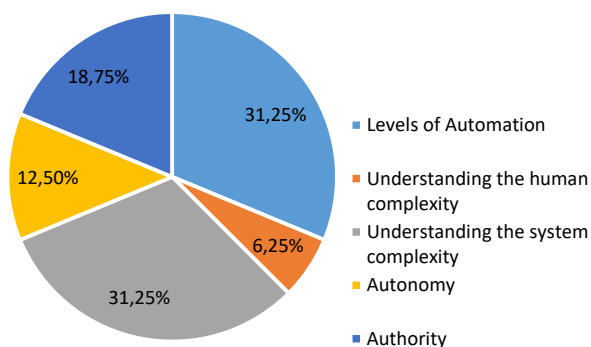


Fig. 9 Factors influencing Human-machine systems for automated equipment's integration security and performance

Technical, organizational and cognitive actions are needed to control the parameters influencing the human-machine system such as the levels of automation, understanding the system complexity, understanding the human complexity, autonomy, and authority. The proposed global approach of human-centered automation helps building Team-Situation Awareness of automated medication dispensing risks, malfunctions, and solutions in order to secure automation: process. It helps medical agents to handle automation issues by a good understanding of the system and its automation process, and a well-documented decision making to ensure an appropriate systems' automation.

VI. CONCLUSIONS AND PERSPECTIVES

This paper has presented delivery automation performance and risk management in complex and risky systems through North Luxembourg hospital center's pharmacy experience of drug delivery automation. The deployment of our human-centered automation approach revealed human-machine parameters to ensure automated equipment's integration security and performance in hospitals. Identified risks are related to Human Machine interaction, technical aspects, and human aspects. Drug delivery automation risks management relies on the control of the level of automation required, the understanding of the human complexity, the understanding of the system complexity, automated solutions autonomy, the hospital pharmacy's authority, and the authority given to automated solutions by the pharmacy. North Luxembourg hospital automation success story was enabled by the management commitment to the automation project, the involvement of the pharmacy in the implementation and improvement of the project, and the close collaboration between the pharmacy and Sinteco's firm to implement the necessary innovation and organizational actions for automated solutions integration security and performance. Automation risks have been identified with the deployment of the proposed methodology. The implementation of an anthropocentric analysis system before automation would have prevented and

optimized the control of risks and malfunctions related to automation.

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