An Interactive Device for Reducing Risk of Infusion Therapy and Blood Transfusions

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Abstract. Administration of high-risk medications and transfusion of blood components are routinary medical procedures that can be potentially harmful to patients due to a set of multifaceted factors, such as, conservation of the medical product, poor asset tracking, and human errors. Although they represent a very small percentage of adverse events, errors and complications associated with transfusion and infusion therapy can cause major morbidity and death.
In the recent years, several reporting initiatives and intervention measures led to the adoption of dedicated processes and tools designed for preventing errors, reducing the associated potential damage, and increasing patient safety. Nevertheless, statistics and reports of incidents demonstrate that infusion and transfusion therapies still demand more effective solutions. In this paper, we introduce an innovative interactive system that aims at reducing risk by taking into consideration human factors that are involved at bedside, such as, fatigue, stress, attention, and cognitive load. Specifically, the proposed solution consists in an attachment that locks a medical container in the prescription phase and prevents access to its content and administration unless all the safety conditions as met. In addition to enforcing safety with a physical barrier, it operates as a visual management tool throughout the process and, specifically, at bedside, where most incidents occur.

Keywords: Risk prevention · Hemovigilance · Pharmacovigilance · Patient safety

1 Introduction

Blood transfusion and infusion therapy are common medical procedures that contribute to saving millions of lives every year; also, they increase life expectancy and improve the quality of life of patients suffering from medical conditions or undergoing surgical interventions. Specifically, over 2 billion blood transfusions and high-risk drug infusions are realized in Europe and United States yearly [1]. Although they involve several risk factors, most of them result in little to no harmful consequences on patients. Nevertheless, despite adverse events happen in a very limited number of cases, blood transfusion and infusion therapy result in 7 million adverse events every year. Primarily, incidents are caused by the conditions of preservation of the medical product and

its handling (e.g., labeling, integrity of the container, expiration date, and conservation temperature). Moreover, risk factors are determined by processes realized over a long supply chain involving multiple stakeholders, steps, and procedures [2], which complicates incident reporting and root cause analysis. Furthermore, equipment accounts for a variety of risk factors [3]. However, for the most part, common incidents are the result of administering the medical component to a different patient, at a wrong time, and with an incorrect dosage [4]. Typically, these types of adverse events are caused by human errors related to distraction, excessive cognitive load, and stress, and mainly occur at the so-called last mile, that is, in the Intensive Care Unit or at bedside [5] [6].

Although consequences vary depending on the cause and type of the event, incidents result in prolonged hospitalization and temporary or permanent conditions, which include several types of disability. Many studies have reported incidences between 0.02 to 0.05 percent, though risk is substantial even if the proportion of patients who experience adverse events is negligible. Moreover, errors, such as, overdosage or transfusion of incompatible blood type, directly or indirectly account for 7000 deaths every year, in the US alone [1].

In addition to consequences affecting patients, adverse events related to blood transfer and administration of drugs cost 600000 US dollars in compensation on average, and they collectively lead to a yearly expenditure of more than 40 billion US dollars [7]. Furthermore, incidents have an impact on the perceived quality of service of the specific hospital involved in a case as well as the entire Health System. Consequently, the World Health Organization and major organizations focusing on Patient Safety started encouraging private and public hospitals to adopt and comply with adverse events policies to reduce the number of incidents, their damage, and their consequent financial and reputation burden [8]. Also, the US Food and Drug Administration, as well as other agencies worldwide, started hemovigilance programs aimed at standardizing definitions, collecting data, and developing prevention measures to ultimately reduce deaths and adverse events [9]. Nevertheless, several studies in the context of blood transfusion [10] [11] unveiled major under-reporting concerns especially in case of reactive incident monitoring. Therefore, many stakeholders advocate for systems that address risk proactively through the whole supply chain and especially in the phases where adverse events are most likely to occur.

Specifically, as root cause analyses established the crucial role of bedside care, research focused on developing prevention measures for last-mile transfusion and infusion practices, as they heavily rely on human attention [12]. To this end, several technical solutions have been developed over the last decade to detect and mitigate errors. Pre-administration controls using standard checklists or electronic tools have been tested in transfusion therapy [13] and they are transferable to infusion therapy as well. However, they do not prevent errors caused by forgetfulness: accidentally skipping the required control does not stop the clinical staff from accessing and administering the medical component. Other solutions, based on safety containers equipped with locks that aim at restricting access to medications or blood components [14] introduce additional tasks that might increase risk, or complicate operations.

In this paper, we describe an innovative hardware/software system that takes into consideration human factors occurring at bedside. By doing so, the proposed system aims at helping hospitals reduce adverse events and their associated costs, increasing

the overall quality of treatment, and improve compliance by enforcing safety and error reporting. We discuss the hardware architecture of the system, that consists in an Internet of Things device that can be attached to a medical container to prevent access to its content. Moreover, we detail its workflow and user interface, which are especially designed for simplifying integration with clinical procedures and, simultaneously, for reducing distraction and other risk factors related to cognitive load. Finally, we discuss the benefits of the proposed system in terms of risk reduction and improvement of staff work.

2 Related Work

In the last decade, several research groups studied transfusion and infusion errors and obtained a taxonomy of adverse events and their causes [15]. This, in turn, enabled root cause analyses that led to the development of guidelines and prevention programs (e.g., the Serious Hazards of Transfusion initiative [16]) aimed at enforcing patient safety throughout the entire process. The adoption of end-to-end electronic transfusion management systems is among the most fundamental practices implemented by hospitals [10], and it supports establishing controls and restrictions that enforce safety of blood and high-risk medication [17]. Also, closing the loop between reactive incident reporting and proactive safety measures [18] has a critical importance in infusion and transfusion therapy [19], as it helps make sense of the data that are being collected.

In addition to studying how to increase quality in the management banks of medical components, the authors of [20] investigated the use of formal methods for automatically analyzing Standard Operating Procedures and predicting the potential occurrence of mode confusion (i.e., misinterpretation of information in the system, execution of inappropriate actions while realizing an activity, and omission of crucial steps of a task), which, in turn, are known to increase the risk of adverse events. Although ensuring the formal correctness of clinical processes improves clinical outcomes and reduces ambiguity, does not prevent risks that are especially related to human factors.

Indeed, the last mile, that is, the bedside or the Intensive Care Unit, is the phase in which errors are most likely to occur and, simultaneously, the last line of defense. Thus, the implementation of several intervention measures especially focused on requiring additional controls at the very endpoint of the process. Several measures aim at ensuring that the administration of the medical component occurs only after verification and confirmation of conditions, such as, the correctness of the component, dose, patient, time, and place [21], as a minimum set of required controls. Paper-based and electronic systems for realizing pre-transfusion and pre-infusion checks have been tested in numerous hospitals and result in significant improvement. The authors of [13, 22] developed an electronic identification system based on Radio Frequency Identification (RFID) that enables verifying the correspondence between the identity of the patient and the blood component before administering a transfusion, and they devised recommendations and guidelines for electronic controls at the bedside.

Unfortunately, patient identification systems alone are not sufficient for reducing risk related to the condition and integrity of the medical product and for preventing other causes of adverse events (e.g., overdosage). Moreover, as they do not prevent physical access to the blood or medical component, they might fail in enforcing safety controls before the therapy is administered to the patient. Conversely, pervasive solutions consisting of attachable devices that can track assets or individuals along clinical processes [18] [23] seem to be more effective. Specifically, the authors of [24] presents a system for equipping blood bags with sensors locking and tracking the medical component, whereas [25] introduces a smart system that uses patient wristbands to verify that the prescription matches the recipient of an infusion or transfusion therapy before unlocking the container of the medical component.

3 System Design and Architecture

In this Section, we describe the hardware and software architecture of the proposed solution, and we detail the design of its main components. The system consists of a device that can be attached to different types of containers for blood and medications to lock their content and prevent access to the medical component, so that it cannot be administered until the necessary safety conditions have been verified. Completing the required controls unlocks the device, which enables removing the attachment from the container and accessing the medical content. As a result, the system acts as a smart barrier that has the purpose of enforcing safety checklists currently utilized in the Intensive Care Unit or at bedside.

The hardware component of the system consists of an electromechanical device that can be applied to different types of containers (e.g., blood bags, medication packages, drug dispensers, and blister packaging) to follow them throughout the different steps of the process, from the prescription phase to administration. Its design was structured according to a modular architecture similar to the device described in [26]. To this end, it is structured in two parts, as shown in Figure 1: a central unit and an accessory. The former controls the operation of the system and, specifically, activates and deactivates a lock depending on whether all the safety checks are positive. The accessory has the purpose of preventing the staff from the medical component by creating a physical barrier that blocks the opening of the container.

The central unit contains all the intelligent components of the system. Specifically, it includes a microcontroller for operating the device, an internal memory storage, a rechargeable battery, a set of LED lights that have the purpose of providing visual information about the type and status of the required security controls, a set of switches for confirming safety checks, an actuator that opens or closes the locking mechanism. The latter can consist in a small motor or in an electromagnetic clamp that secures both endpoints of the accessory and prevents their removal from the central unit.

The electromechanical components are designed to be enclosed in a water-resistant plastic container so that the central unit be reused after appropriate cleaning procedures. Each LED indicates a necessary safety check (e.g., patient identification) that must be

realized before the container can be unlocked, and a corresponding switch enables marking the condition as verified. When all the switches and LEDs indicate that the checklist is complete, the central unit releases the lock, so that the accessory can be removed from the central unit and it can be opened and removed.

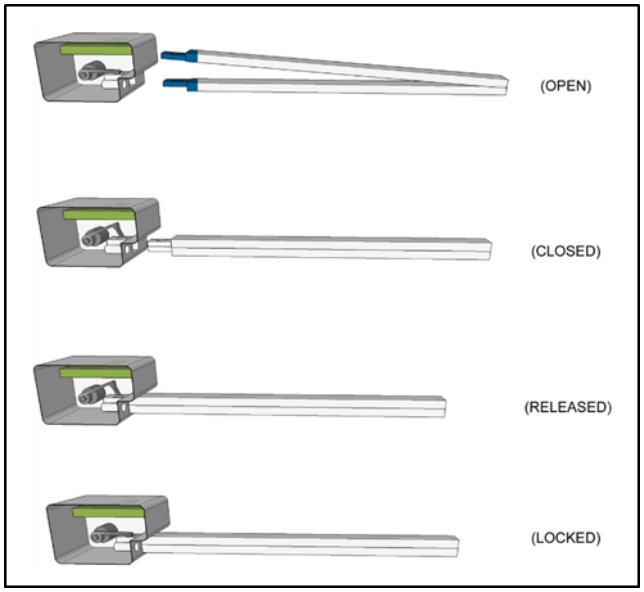

Fig. 1. Overview of the proposed system in different configurations: a standard attachment enables connecting the central unit (on the left) to the accessory (on the right) and preventing access to the medical content. Accessories can be customized to be utilized with diverse medical containers in in different shapes and materials.

Additionally, the central unit can incorporate communication systems for interconnecting the system with external devices and exchanging information with them. As a result, the system can be integrated with end-to-end blood and medication management systems, as well as with asset-tracking software. Furthermore, the system supports adding sensors for monitoring variables (e.g., temperature) that can impact the quality and integrity of the medical component in the different phases of the process.

The attachment has the sole purpose of preventing physical access to the component. By doing this, the system enforces patient safety checks and prevents human factors, such as, fatigue and stress, from causing events that could lead to errors (e.g., checking the wrong bag or skipping some checks). The device was initially designed for securing blood bags. As shown in Figure 1, the attachment consists in two rigid arms that create light compression on the bag and stops the blood from accessing the intravenous lines. However, the shape and material of the accessory can vary depending on the type of container (as described in Figure 2), so that they can be utilized with different medical components, such as, injection syringes, various types of pill and medication dispensers, and even larger containers (e.g., organ transport coolers). Also, different types of

custom locking accessories can be realized to match the size and shape of specific containers. For instance, an elastic rubber band can be utilized for capsule containers and other types of dispensers. Regardless of the type of accessory, the standard attachment located at the endpoints provides a universal adapter, so that the central unit can be utilized with multiple containers. Accessories can consist of reusable or disposable medical grade material. The system supports manual overriding if standard procedures for unlocking the device fails or in case of malfunction. Overriding events can be tracked by the central unit, to report any failure or attempt of tampering with the system.

The system intervenes at the beginning of transfusion and infusion procedures: when a new request for medical component is received, the specialist responsible for dispensing it (e.g., hematologist) applies the appropriate accessory that matches the medical container and activates the locking mechanism by inserting it in the slot of the central unit. As a result, the LEDs indicating the safety checks show a red light to signal that the container will be locked until all the items are cleared. When the container arrives at the ward, some items can be pre-checked and ticked off (e.g., integrity of the medical product, or correct dose) by activating the corresponding switches. Finally, the personnel administering the infusion or transfusion can realize the last controls (e.g., correct patient), which releases the accessory.

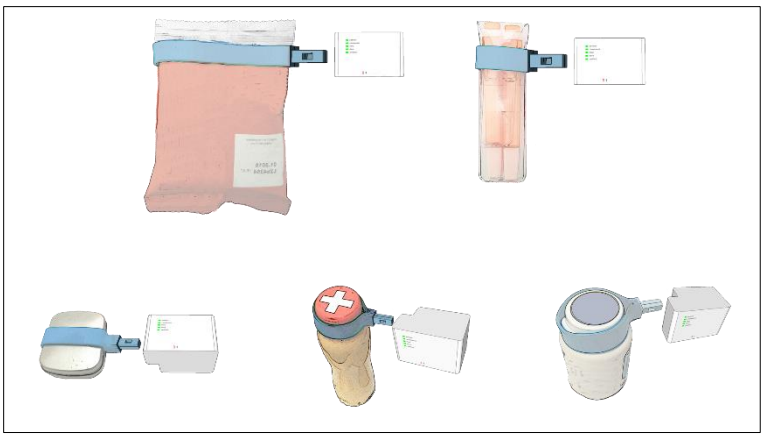

Fig. 2. The proposed system applied to different types of containers, such as, injection syringes and blood bags (on the top), and various types of pill and medication dispensers (on the bottom).

4 System and Human Factors Evaluation

In order to evaluate the applicability of the system, we involved members of the clinical staff to join the design since the initial phase. Specifically, we analyzed current Standard Operating Procedures for infusion and transfusion therapy and we mapped the entire process from request to administration. Our analysis focused on understanding the human factors occurring in each step of the infusion and transfusion supply chainwith the

objective of identifying the items that contribute the most to increasing the occurrence of human errors.

The first step is the prescription phase, in which a medical component for a specific patient is requested to the dispensing unit (e.g., the internal blood bank of a hospital). Nowadays, management systems enable to automatically verify the correspondence between patient information (e.g., blood type) and the type of blood or medication that is being requested, and they help prevent most of the errors that are caused by distraction, interpretation of handwriting. As a result, the proposed system would not apply to this step. Nevertheless, the device can be effective in addressing other factors, such as, preservation of the medical component, that involve hazard for the patient: by attaching the system to the container when the medical product is packaged, the propose device can collect information that would otherwise be difficult to track (e.g., temperature).

Subsequently, the request is received by the internal blood or medication storage ward and the medical component is retrieved, checked, labeled, and dispensed. In this step, the staff experiences some degree of cognitive load that is directly proportional to the type and complexity of the procedure, which may vary depending on the organization. Moreover, in general, cognitive load is directly proportional to the number and rate of requests in a given time frame. Errors in this step are caused by simultaneously processing multiple medical products: when two prescriptions are served in parallel, the operator can swap containers and dispense the wrong one. In this context, the proposed system alleviates the issue: applying the device to a container and locking it helps the staff identify the medical components that have already been processed. By doing this, the proposed solution acts as a visual management tool that labels requests that are ready to be dispensed and helps the staff separate them from medical components that are in the queue.

The same type of issue impacts the next phase of the process, when the medical component reaches the destination ward and the clinical staff realizes preliminary controls: as multiple blood bags for different patients can simultaneously be transported on the same cart, some containers could be accidentally checked twice, whereas others could be skipped. By activating the switches on the central unit of the device, the staff can change the status of a container; the presence of LEDs and the implementation of a traffic-light system helps easily identify the items that have been processed. In addition to helping distinguish the components that have been verified, the central unit acts as a visual tag that enables the staff in the next phase to detect if a step was missed.

Finally, when the container reaches the last mile, preventing physical access to the medical component before all the necessary safety checks are successfully realized has a three-fold purpose: (1) enforcing the checklist and its importance, (2) creating a sequential check-unlock-administer pipeline that prevents process parallelization (main cause of incidents occurring due to accidentally swapping container), and (3) recognizing the status of the container in the pipeline, so that the medical component that has been checked can be identified as ready to be administered.

As a result, the system simultaneously acts as a physical barrier and as a visual management tool. In this regard, the device is designed to address two key principles that underpin every stage of the administration process, that is, positive patient and component identification and support to communication. Moreover, instead of changing the process and requiring the adoption of a specific technology for verifying patient safety requirements as detailed in [13], the proposed solution is agnostic about the specific procedure and checklist utilized for infusion and transfusion therapy. Consequently, it can seamlessly integrate with current clinical processes and achieve higher level of acceptance from the clinical staff. Although the system focuses on reducing risk of erroneous administration of blood and high-risk medications by specifically taking into consideration several adverse events caused by human factors involved in the last mile, it addresses patient safety from the initial steps. Furthermore, by visually tagging a medical container and changing its status along the process, the device can help recognize errors and prevent them from propagating further.

5 Conclusion

In this paper, we discussed a solution that is especially designed to reduce errors due to human factors during the last mile of the administration of an infusion or transfusion therapy, that is, at bedside or in the Intensive Care Unit, where most of adverse events that can be prevented occur.

To this end, the proposed system consists of an interactive hardware device can be attached to any blood bag or pharmaceutical container to lock it and prevent access to its medical content unless verification of necessary safety conditions succeeds (e.g., correspondence of patient, time, and dosage). Before administering the medical component, the system requires the staff to execute a multi-factor safety check that can unlock the container and enable access to its content.

Specifically, the purpose of system is to target the most critical phase and prevent adverse events in the last mile, with specific regard to human errors. Nevertheless, as blood and high-risk medication have a long supply-chain, the system is designed to integrate with end-to-end infusion and transfusion management processes and systems used by hospitals and blood centers [10]; moreover, it can incorporate additional sensors and data transmission devices that can enable connecting and communicating with external devices and software systems, track the entire process, and provide the clinical staff with asset management features that simultaneously enable doctors and nurses to assess and report about the quality and integrity of the medical component.

The system has several advantages from a human factors standpoint: it was designed to be extremely simple to operate and to seamlessly integrate with current procedures; it does not introduce any complexity other than attaching and removing the accessory from the medical container. Moreover, the modular attachment architecture supports using a single interface with many different types of medical products and containers, whereas other systems are specifically targeted for a single purpose and their adoption requires the staff to learn and use multiple different products.

Indeed, the proposed solution is potentially subject to the same limitations of other technology, that is, the introduction of an additional step, which might result in unexpected risk elements that ultimately affect patient safety. Therefore, in our follow-up work, we will study applications of the proposed system in different scenarios, in hospital settings and at home, to evaluate its effectiveness in actually preventing adverse events.

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