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Towards a novel spontaneous medication error reporting tool for enhancing patient safety

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Abstract—Improving patient safety and quality of care has become a priority for healthcare organizations, given the frequency and potential severe clinical consequences of medication errors and adverse drug events during the Medication-use Process. Medication error reporting can be one most effective strategies to achieve these goals. Indeed, high error reporting rates indicate a positive safety culture rather than an unsafe healthcare environment. It is through the identification of these errors safety barriers can be put in place to prevent a similar event from occurring in the future. However, current healthcare organizations still suffer from a lack of attention in this context, especially in establishing a digital tool dedicated to medication error reporting, which is the motivation for the work described in this paper. The latter proposes a novel tool to make the local reporting of medication errors easier and encourage reporting these errors with the healthcare professionals' confidentially. The overall response to the tool provided was positive from the staff participating.

Index Terms—Medication-use process, Medication error, Adverse Drug Event, Patient Safety, Healthcare organization

I. INTRODUCTION

The Medication-Use Process (MUP) is one of the most complex processes in healthcare organizations [1]. The MUP is a multidisciplinary process involving numerous practitioners and comprises several steps. This complexity increases the likelihood and number of Medication Errors (ME). The latter may occur during any step of the MUP, from medication prescription to administration, and can be at the origin of an Adverse Drug Event (ADE) with potentially severe clinical consequences for the patient.

Medication errors have become a serious public health problem that substantially threatens patient safety. Medication errors may cause considerable patient morbidity, mortality, and increased healthcare costs [2]. One of the main goals of the French Ministry of Health is to reduce medication errors and improve patient safety in their healthcare medication-use process [3]. It is challenging to uncover a consistent cause of errors and, even if found, to provide a consistent, viable solution that minimizes the chances of a recurrent event [2]. However,

by reporting these events, learning from them, and working toward preventing them, patient safety can be improved [4].

Indeed, reporting medication errors is considered as one most effective strategies to improve patient safety [2]–[5]. These reports help to understand medication errors as well as contributing factors. The main objective is to establish a culture of safety that focuses on system improvement by viewing medication errors as challenges that must be overcome. The consequence of not reporting medication errors is that the errors could continue to occur [3].

In this context, current healthcare organizations still suffer from a lack of attention regarding establishing a spontaneous digital tool dedicated to medication error reporting. To fill the shortcoming and to assist healthcare professionals in ensuring patient safety, we suggest, in this work, a novel digital tool for local medication error reporting, which is a preliminary result of our research in this field. The proposed tool aimed to increase awareness regarding reporting medication errors, facilitate reporting, maintain a database to analyze the contributing factors associated with these errors, and keep confidentially reporting.

This paper is structured as follows. Section II provides an overview of the medication-use process, related medication errors and adverse drug events, and the importance of medication error reporting. Section III presents the adopted framework for medication error reporting, which might arise from a given medication-use process. Finally, the paper is closed with a conclusion and some directions for future work.

II. BACKGROUND

A. Medication-use Process

According to the French decree of April 16, 2011, the Medication-use Process (MUP) is defined as “a process combining multidisciplinary and interdependent stages ... aiming for a common objective: the safe, appropriate and efficient use of medication in the patient treated by a healthcare organization”. In the same way, in [6], the MUP is defined as “the fundamental

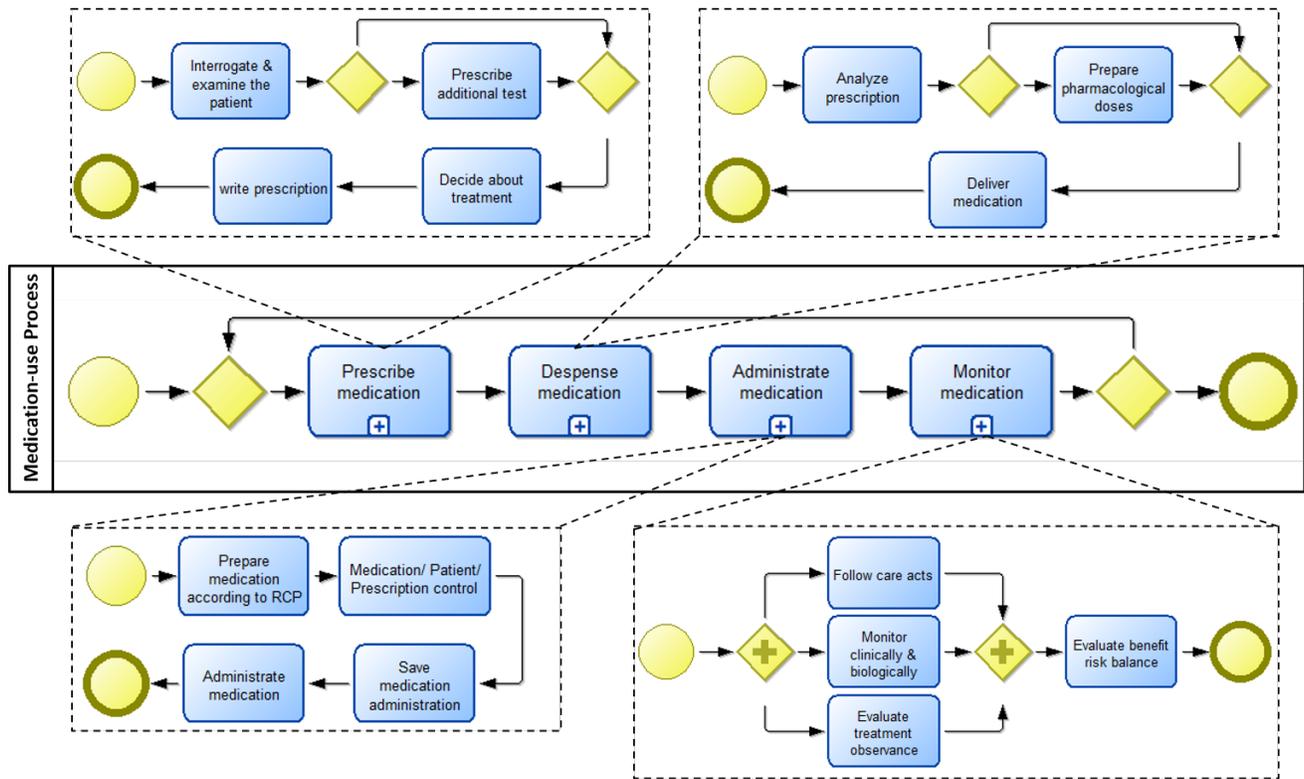


Fig. 1: Medication-use process model described with BPMN

system that provides the basis for safe medication use within the healthcare environment” [6]. The MUP consists of a complex and multidisciplinary process involving numerous healthcare professionals. The MUP has the following four major steps: (i) prescribing/transcribing – entering and processing prescriptions for patient care; (ii) dispensing – preparing medications from a prescription for the patient; (iii) administration – administering and documenting the administration of medication; and (iv) monitoring – monitoring patients for adverse events and therapeutic effectiveness [6].

This process is considered one of the most complex care processes, in particular of: the diversity of the pathology, the intervention of various healthcare professionals (the prescribing doctor, the dispensing pharmacist, the nurse’s aides, the nurse who administers the medication, and the patient), and the chain of numerous process steps taking place for a large number of medicines to be delivered to patients by different workers in different geographical places [6]. Figure 1 represents the macro-steps and some related activities of the MUP as defined in the French National Authority for Health report [7] using a Business Process Model and Notation (BPMN) model.

The complexity of this process can lead to the occurrence of Medication Errors (ME). These MEs can be the origin of Adverse Drug Events (ADE), which can have serious clinical consequences for patients. It has been established that medicine is one of the leading causes of severe ADE for hospitalized patients [7]. As defined in [8], safe control of the MUP requires

a good knowledge of the ME and the ADE. It will be a prerequisite to capture the knowledge needed to investigate any error and possibly get some benefits from the experience.

B. Medication Error and Adverse Drug Event

Over the last decade, Medication Errors (EMs) have become an increasingly newsworthy topic. With heightened public and political attention on patient safety and medical error, hospitals and medical professionals have been thrust into the spotlight and face increasing pressure to safeguard the MUP.

There is no agreement on what constitutes a Medication Error (ME). A comprehensive literature examination discovered 26 alternative terminologies for a Medication Error [9]. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) in the USA [10] defined medication errors as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, Or consumer; such events music be related to professional practice, healthcare products, procedures, and systems”. These errors might be related to professional practice, healthcare products, procedures, and processes, such as prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and usage.

According to the American Society of Health-Systems Pharmacists guidelines, MEs compromise patient confidence in the healthcare system and increase healthcare costs. The problems

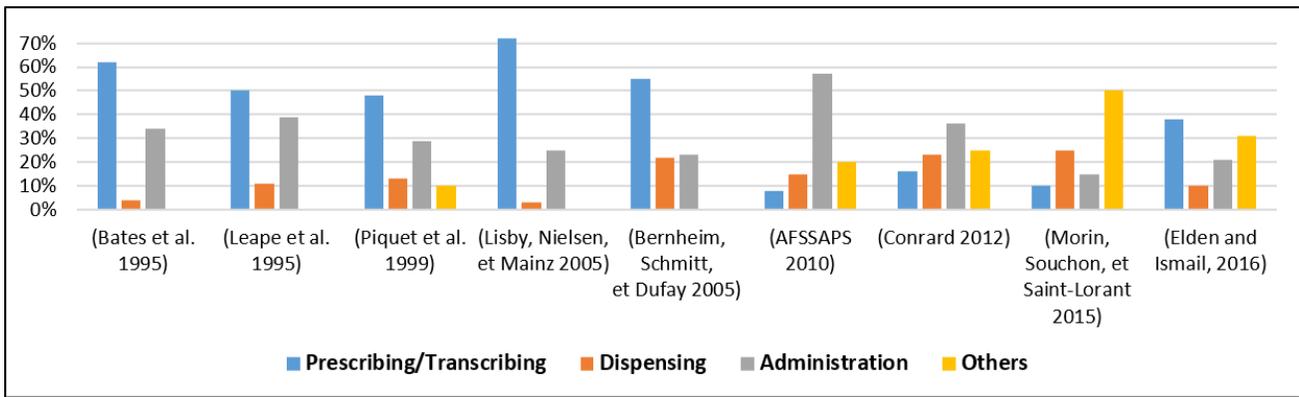


Fig. 2: Medication Errors by MUP macro-steps.

and sources of MEs are multidisciplinary and multi-factorial. Medication Errors may occur during any step of the MUP, from medication prescription to medication administration, and may or may not lead to an Adverse Drug Event (ADE). Medication errors can also cause strain and emotional stress to the nursing staff that experienced the error [3]. Indeed, MEs refer to the most frequent cause of preventable adverse events caused by medications [11].

In 1995, the NCC MERP announced a referential for ME classification later translated by the French Society of Clinical Pharmacy (FSCP) in 2006 [12]. [13] and [12] differentiate four approaches to classify ME:

- Classification by MUP macro-steps where errors occur. Indeed, several national and international studies confirm that MEs arise in all the steps of the MUP. Figure 2 presents a summary of these studies [8], [14]–[21];
- Classification by error types. According to [7] 13 types of ME can be distinguished;
- Classification by severity level. To describe the severity of the clinical consequences on the patient, the FSCP defined nine categories from A to I, where category I corresponds to the highest level of severity: a patient death.

An “Adverse event” is any event that resulted from an error that reached the patient but may or may not have caused harm, including medication errors [3], [22]. An “adverse drug event” (ADE) is specific to medications. Several studies have shown that most of the adverse events for hospitalized patients result from medication error(s) [3], [22]. ADEs may result from medication errors or adverse drug reactions in which there was no error [14]. ADEs consequences can be substantial, including hospital admission, prolonged hospital stay, additional resource utilization, and lower patient satisfaction [23].

Following these observations, we propose an excerpt of the meta-model describing a ME in its context in Figure 3. A complete ME meta-model and further information on MUP can be found in [24], [25].

Many international studies have described the frequency and the cost of MEs and ADEs in the MUP [26]. Starting in 2000, the Institute of Medicine began publishing a series of reports on quality in healthcare. The first one, “To Err

is Human”, increased the awareness of unacceptably high rates of MEs and sentinel events in U.S. hospitals with about 44,000 – 98,000 deaths annually attributed to these preventable mishaps [27]. The second one, “Crossing the Quality Chasm”, made five significant points: errors are common and costly; systems cause errors; errors can be prevented, safety can be improved, and medication-related adverse events are the single leading cause of injury [28]. The most recent one, “Preventing Medication Errors”, attempts to think about what needs to be done to reach the next level of medication safety [29]. This work announced that at least 400,000 preventable adverse drug events in hospitals annually, or approximately one medication error per patient daily. That finding probably had the most significant impact on the general public [29].

In 2017, the Agency for Healthcare Research and Quality (AHRQ) estimated that 1.3 million people are injured annually from medication errors [30]. In addition, the World Health Organization (WHO) estimates the annual cost of medication errors at 42 billion dollars (US \$) worldwide, which would represent nearly 1% of all health expenditures worldwide [3]. MEs are considered the third leading cause of death in the United States of America (USA), after heart disease and cancer [31].

The analysis of international studies on EM and ADE shows these events’ complex and uncontrolled aspects. Indeed, healthcare leaders cannot put safety nets in place without understanding why MEs are occurring to prevent patient harm. Awareness of the occurring errors will also allow the facility leadership to be more proactive than reactive in error prevention.

To deal with this international public health problem, healthcare organizations need to establish a culture of safety that focuses on system improvement by viewing Medication errors as challenges that must be overcome rather than harboring a culture of blame, shame, and punishment. All individuals on the healthcare team must play a role in making the provision of healthcare safer for patients and healthcare workers [32].

Medication error reporting can be a part of improving patient safety and quality of care. It is through the identification of system-wide errors that safety barriers can be put in place

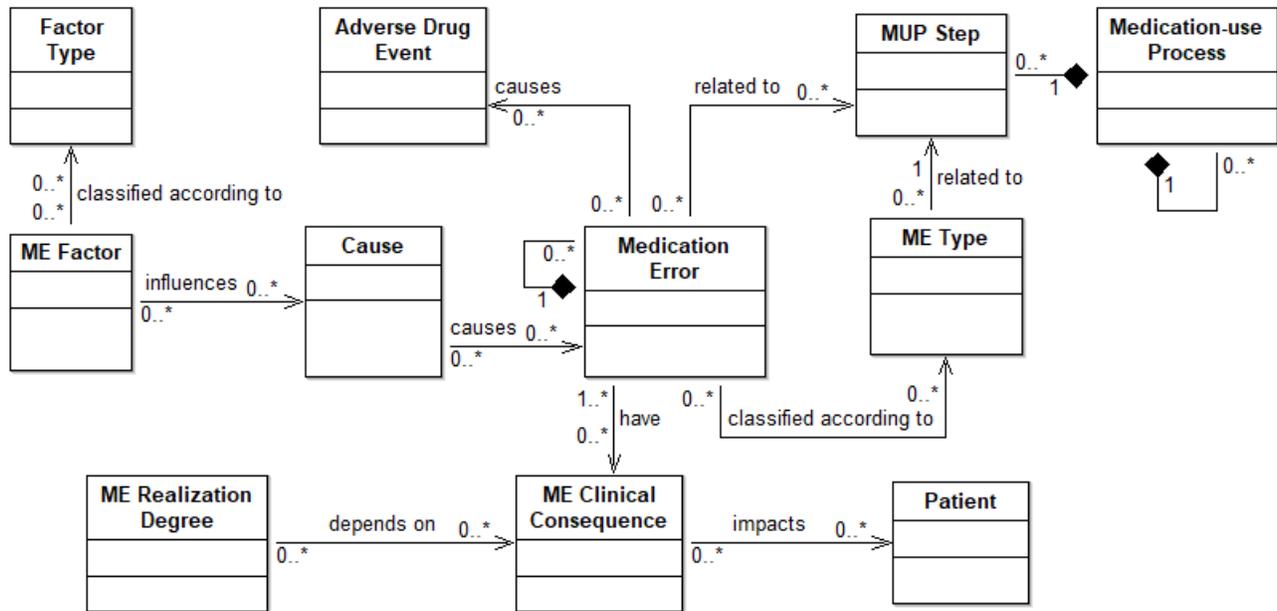


Fig. 3: Excerpt of medication error meta-model.

to prevent a similar event from occurring in the future. The following section describes this strategy's importance.

C. Safety Patient and Medication Error Reporting Importance

As previously presented, MEs create a serious public health problem that substantially threatens patient safety. By understanding MEs, learning from them, and working to prevent them, patient safety can be improved [4]. Indeed, patient safety and quality improvement initiatives have focused on reducing medication errors, which can be investigated using ME reporting [5].

In its landmark 1999 report, To Err is Human, the Institute of Medicine put forward that an effective system for reporting these errors is essential to learn from MEs and prevent their recurrence [28], [31]. In the same way, multiple other studies [3], [5], [31] recognized reporting medication errors as one most effective strategies to improve patient safety and identify and prevent system errors. Indeed, if medication errors are reported and managed by a modification of the system, a decrease in the frequency and concomitant errors associated with it will occur [3], [5], [31]. Also, these reports help to understand medication errors and contributing factors. It is through the identification of system-wide errors that safety barriers can be put in place to prevent a similar event from occurring in the future [3].

The main objectives of reporting medication errors are:

- Identifying system-level, provider, medication, and patient factors that can be used to develop and implement prevention measures;
- Collecting additional information regarding medication errors;
- Maintaining a database to analyze the contributing factors that contribute to these errors;

- Using this information to develop measures to avoid future medication errors and improve patient safety;
- Keeping a culture that works toward recognizing safety concerns and implementing feasible solutions rather than holding a blame, shame, and punishment culture;
- Establishing a patient safety culture that focuses on system improvement by perceiving medication errors as challenges to be conquered;
- Involving all healthcare team members in making health-care safer for patients.



Fig. 4: Levels of medication errors reporting.

In French healthcare organizations, some dedicated electronic reporting tools have been proposed to assist healthcare professionals in ensuring patient safety. Examples of such tools are: “eSIN” for healthcare-associated infections, “eFIT” for events relating to haemovigilance incidents and accidents, “e- DO” for the declaration of an HIV infection, and “Teleservices.asn.fr” for significant radiation protection events, etc. However, to our knowledge, there is currently no dedicated digital tool for medication error reporting. All the media used are in paper format and do not enable knowledge to be capitalized around the declared ME. Figure 4 presents the three main levels of ME reporting:

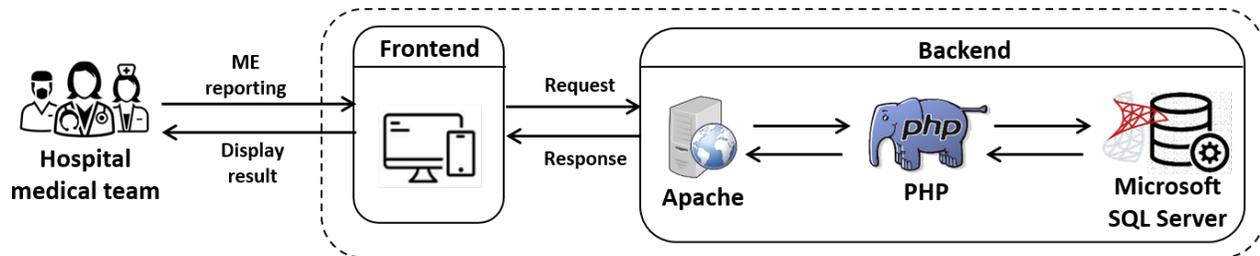


Fig. 5: Medication errors reporting tool architecture.

- At the local reporting level, healthcare professionals report to the structure in charge of risk management in their healthcare organization at the occurrence of a ME or an ADE. The reporting methods can vary from one healthcare organization to another (a reporting form, telephone call, information communicated orally, etc.). The analysis of the causes of a Me is then carried out with the support of the risk management structure: analysis of the root causes, development, and implementation of corrective measures. Afterward, healthcare organizations report serious MEs and ADEs to the French Regional Health Agency.
- At the regional reporting level, the French Regional Health Agency evaluates reports, if necessary, with the reporter and considers possible measures. An in-depth analysis of reported events is also carried out, and an action plan is then implemented. Afterward, the French Regional Health Agency reports serious risks of medication errors and adverse drug events to the French National Authority for Health (HAS).
- At the National reporting level, the HAS receipts and records anonymized risks of MEs and ADEs sent by the French Regional Health Agency. These risks are then: (i) analyzed by a permanent committee of HAS experts, (ii) identified and prioritized in the risks database, and (iii) treated by setting up a work program and recommendations to improve patient safety (Professional recommendations, solutions for patient safety, training or information materials, etc.)

The efficiency of the action plans and corrective measures set up to manage ME at the regional or national levels depends especially on the local ME reporting. Indeed, the high local error reporting rates indicate a positive safety culture rather than an unsafe healthcare organization.

In this context, this work intends to implement a local medication error reporting tool for all qualified healthcare professionals. The outcomes were to increase medication error reporting and address the staff's perception of medication errors.

III. PROPOSED FRAMEWORK AND PRELIMINARY RESULTS

The proposed tool aims to provide healthcare organizations with a digital tool for collecting data on medication errors that may occur during the Medication-use Process. To this end, the knowledge structure was defined to report a medication error without omitting any dimension of its representation.

The reporting tool aims to provide a basis for identifying the failures that led to the medication error as quickly as possible and understanding the sequence. This is a reasonably complex task given the structural and organizational heterogeneity of data sources around the Medication-use Process and medication error. The proposed reporting tool focuses on specific medication error parameters and metrics (context, causes, factors, type, consequences, etc.). The choice of techniques and variables to implement for this reporting constitutes a complex task. This choice will determine the performance of the medication error management process.

In this work, the proposed tool was formulated to make reporting medication errors easier and encourage reporting errors with the healthcare professionals' detailed confidence. We adopt a framework based on the Apache web server, the Hypertext Preprocessor (PHP) scripting language, and the Microsoft SQL Server technologies to implement the proposed tool. Figure 5 presents the proposed ME reporting tool architecture.

To evaluate the capability, feasibility, and relevance of the preliminary version of the proposed reporting tool, an experiment was carried out in collaboration with the French Intercommunal Hospital Center of Castres-Mazamet (CHIC) and was focused on reporting medication errors related to the MUP in a geriatric ward.

This experimentation revealed that the hospital medical team easily adopted the tool, which enabled them to quickly report medication errors anonymously and ensure the healthcare professionals' confidentiality. Users also argue about the gain they will achieve by collecting information about medication errors and maintaining a database to analyze their contributing factors. Indeed, it allows them to have a comprehensive vision of ME. It has also been valued as a useful reporting tool for improving the quality of pharmacological management as well as the patient care processes.

CONCLUSION

Medication errors are a leading source of avoidable harm in healthcare worldwide. To assist healthcare professionals in ensuring patient safety, we introduce, in this paper, a new digital tool for medication error reporting, which is a preliminary result of our research in this field. The proposed tool aimed to: increase awareness regarding medication errors and facilitate their reporting.

To evaluate the usefulness and relevance of this framework, we used the proposed tool to report some medication errors in a real-world hospital medication-use process. Users' feedback has shown that the proposed tool can overcome the limitations of current practices for medication error reporting.

The positive feedback we have received, in collaboration with our healthcare partners, motivates us to continue the improvement of our tool to integrate additional functionalities, create a rich database, and use this data to set strategies to reduce future medication errors and improve patient safety. These perspectives will be the subject of future research.

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