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Original Article

Development and multi-centre evaluation of a method for assessing the severity of potential harm of medication reconciliation errors at hospital admission in elderly

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ABSTRACT

Background: Medication reconciliation is a powerful process to correct medication errors (ME) resulting from miscommunicated information at transitions of care. This study aims to develop and evaluate a scoring method for assessing the severity of potential harm of ME intercepted by medication reconciliation at hospital admission in elderly.
Methods: The development of the scoring method was based on a literature search and the creation of a list of high-risk drugs used in outpatient care. The evaluation of the method was carried out in 7 French hospitals and was based on two criteria: the inter-rater reliability and acceptability. The assessment of the inter-rater reliability was based on intra-class correlation coefficient (ICC) calculations. Each hospital prospectively enrolled the 10 first patients aged 65 or older presenting with at least one ME. Seven blocks of 10 patients were formed. After randomization, each block was rated by practitioners from 3 hospitals. The assessment of the acceptability was based on a satisfaction questionnaire.
Results: A clinical algorithm was developed. The inter-rater reliability of the method was validated by the overall agreement of the 7 hospitals ratings. The agreement was at least substantial (ICC > 0.60) and in most of cases almost perfect (ICC > 0.80). The acceptability of the method was judged as satisfactory.
Conclusion: This multi-centre project has validated an instrument for assessing the severity of potential harm of ME intercepted by medication reconciliation. This will allow studies to be conducted with large cohorts of patients in order to develop epidemiological databases of ME of potential clinical significance.

1. Introduction

Medication reconciliation is a powerful process to intercept and correct medication errors (ME) resulting from incomplete or miscommunicated information during transitions of care (hospital admission, transfer and discharge) [1]. At admission, medication reconciliation

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provides best possible medication histories (BPMH) which reflect accurate and complete lists of all medications taken by the patients in ambulatory care prior to hospitalization. This process incorporates a necessary partnership between hospital practitioners and health professionals from ambulatory care (mainly pharmacists and physicians) and collaboration with patients and families [2].

The evidence presented in the literature shows that medication reconciliation contributes to the quality of patients' care and therefore to the safety of drug therapy management. However, the impact on clinical outcomes resulting from this process has to be more precisely demonstrated [2].

Scoring methods for assessing the potential clinical impact of ME have been described in the literature [3]. They show that 12.8% to 66.2% of ME intercepted and corrected by reconciliation at hospital admission or discharge could cause potential damage to patients [3,4]. The wide range of results is mainly due to the fact that different scoring systems have been developed and used in single studies. Several of them have examined the probability of ME to cause patient injury (improbable, unlikely and probable) [5–10] while others have assessed the potential severity of ME (going from minor to serious deleterious potential effects) [11–20]. When using a scoring method to evaluate the potential severity of ME, the number of levels of measurement ranges from 3 to 9. Eleven studies have chosen a 3-point scale [4–10,12,18–20], one a 4-point scale [16] and 4 a 5-point scale [13–15,17]. In all studies, the lowest level represents cases without potential effect and, the highest level, cases of ME that would result in death. Regarding the qualification of persons assessing the potential clinical impact of ME, some studies have involved only physicians [5,6,8,11,14,15], others both physicians and pharmacists or other health care professionals [7,10,12,13,16–20]. Moreover, individual scorings have been found in 11 studies [5–8,12,14–17,19,20] while consensual ratings where all evaluators meet together have been found in 4 studies [10,11,13,18]. None of these scoring methods has been validated and used in a multi-centre study.

In view of these heterogeneous data and considering the value of having a standardized and multi-centre validated tool, we have considered that the development and assessment of a new scoring method were required to accurately determine the clinical significance of harm prevented by medication reconciliation.

Any measurement tool must be reliable (i.e. in our case, able to produce the same result for the same ME whoever evaluates the error and whatever the place) and practical. Considering these two criteria, the aim of the project was first to develop a scoring method for assessing the severity of potential harm of ME at hospital admission and then to evaluate its inter-rater reliability and acceptability in a multi-centre study.

2. Methods

This project was part of the Medication Reconciliation (MEDREC) programme of the "High-5 s" initiative [21] supported by the World Health Organization (WHO), World Alliance for Patient Safety, coordinated in France by HAS (the French National Authority for Health) and supervised by OMEDIT Aquitaine (a centre for monitoring the use of medicines and medical devices located in Aquitaine, France).

It was conducted from January 2012 to June 2014 in the 7 French hospitals involved in MEDREC project: Compiegne Hospital, University Hospital of Grenoble, Lunéville Hospital, University Hospital of Nimes, University Hospital of Bichat Claude Bernard Paris, Saint Marcellin Hospital and University Hospital of Strasbourg.

In each of these 7 hospitals, medication reconciliation at patient's admission was performed according to standard operating protocols (SOPs) developed within the context of the "High-5 s" initiative and in agreement with the French Society of Clinical Pharmacy (SFPC) guidelines [22]. Patient population was constituted by those aged 65 years or older admitted through the emergency department to inpatient services. BPMH were obtained by clinical hospital pharmacists within 24 to 48 h of admission to hospital, using multiple sources of information and including all prescriptions, over-the-counter and complementary medications used regularly or when required.

2.1. Development of the scoring method

The development of the scoring method was based on a literature search and the generation of a high risk-drugs list.

2.1.1. Literature search

A review of the literature was carried out (Medline database PubMed, key words used: medication discrepancies potential risk, medication discrepancies clinical impact, medication discrepancies potential clinical impact, medication errors admission potential impact, medication errors admission potential risk, medication errors admission potential clinical impact, medication reconciliation discrepancies potential clinical impact, medication reconciliation discrepancies potential clinical risk).

Seventeen articles of interest were identified and used by Lunéville Hospital and University Hospital of Strasbourg to develop the scoring method [4–19]. The works of scientific societies such as the SFPC or the AHRQ (Agency for Healthcare Research and Quality) were also consulted [22,23].

2.1.2. Generation of a high risk-drugs list

The Delphi process is a method allowing a consensus opinion to be reached among experts through an iterative and anonymous process known as rounds [24]. This process was conducted to generate a list of high-risk drugs to be used as part of the scoring method. Firstly, a preliminary list containing 33 classes commonly used in ambulatory care (mainly drugs taken orally but also injectable drugs) was submitted to a panel of experts. Two rounds were then carried out to generate the high-risk drugs list considering 2 distinct potential types of ME: error by omission and error of dose.

2.1.2.1. Experts: panel selection. Forty-six experts with recognized experience in medication reconciliation or in clinical pharmacology were invited to build the high-risk drugs list.

2.1.2.2. Data collection and analysis

2.1.2.2.1. First-round. The preliminary list submitted to the experts was sent by e-mail. These experts were invited to rate each drug class on a 5-point Likert scale in two situations: error by omission and error of dose. This scale ranged from a score of 0 (harmless drugs e.g. without potential risk for patients in cases of error by omission or error of dose) to 4 (extremely harmful drugs e.g. with a high potential risk of harm for patients). After the first round, mean and standard deviation (SD) obtained for each of the 33 drugs classes were calculated considering separately the 2 potential types of ME (error by omission or error of dose). Drugs classes, for which mean scores were greater than 2.55 and SD lower than 1.00, were considered as high-risk drugs. During the first-round, experts were also invited to make comments.

2.1.2.2.2. Second-round. Drugs classes for which consensus was not reached according to the SD values (i.e. SD ≥ 1.00) in one or both situations (error by omission or error of dose) were further evaluated by the experts. The mean scores (and SD) obtained in the first round and statements added by the experts were presented anonymously, enabling the participants to reconsider their previous responses. The answers provided by the experts in the second round were evaluated by using the same procedure described above.