

# Targeting of under-75 years for the optimization of medication reconciliation with an approach based on medication risks: An observational study

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**THERAPIES** 

**HEADING: Clinical pharmacology** 

Targeting of under-75 years for the optimization of medication reconcil-

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study

Optimization of medication reconciliation

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# **Summary**

Purpose.-. To date, how medication reconciliation (MR) could be prioritized in younger patients remains poorly evaluated. This study aimed at assessing whether a MR prioritization strategy based on the identification of high-risk medication at patients' admission treatment could be of interest in nonelderly patients. Method.-. This prospective study was conducted between July and September 2017 in an internal medicine unit at Bordeaux teaching hospital. All patients aged 16 to 74 years and receiving at least two long-term treatments at admission were considered eligible; High-risk medications were defined on the basis of a pharmacovigilance study, which identified the drugs most involved in serious adverse effects reported in the Nouvelle-Aquitaine region in non-elderly adults. They included antithrombotics, analgesics, antipsychotics and cardiac therapies. MR-induced treatment changes were compared according to the existence of high-risk medications at admission in study participants. Results.-. Among the 92 study participants, 46 presented with high-risk medications at admission (median age 66 years, IQR 58-70) and 46 without such (median age 54 years, IQR 47-64). High riskmedications (HRM) existing at admission were antithrombotics (52.2%) and antipsychotics (22.4%). MR resulted in treatment changes in 37% of patients admitted with at-risk medications vs. 8.7% of those admitted without such (p = 0.001). Overall, the mean number of treatment changes performed after MR was of 1 (95%CI 0.4-1.6) in patients with high-risk medication at admission and of 0.2 (95%CI 0-0.4) in patients without such. MR-induced treatment changes assessed as clinically major at least once by pharmacists or clinicians was greater in HRM group (43.5%) than in non-HRM group (31.6%). However, the consistency was low between clinicians and pharmacists, especially to distinguish the clinical importance of significant and minor interventions. Conclusion.-. Targeting high-risk medications at admission appeared efficient for the prioritization of MR in non-elderly patients hospitalised in internal medicine.

#### **KEYWORDS**

Pharmacology; Clinical; Medication reconciliation; Medication errors; Adverse drug reactions; Drug safety; pharmacovigilance.

## **Abbreviations**

ADRs: adverse drug reactions

DP: dossier pharmaceutique (shared pharmaceutical file)

HAS: Haute autorité de santé

HRM: high-risk medication

IQR: interquartile ranges

MR: medical reconciliation

REMED : Revue des Erreurs liées aux Médicaments Et Dispositifs médicaux associés

SADRs: serious adverse drug reactions

#### Introduction

To reduce the number of medication errors associated with the prescription and delivery of drugs, several measures have been introduced over the last years, including patient education, physician awareness and pharmaceutical support in care units [1]. Among these measures, in certain contexts, medication reconciliation (MR) has proven its effectiveness in reducing treatment discrepancies and medication errors [2] and in improving patient safety [3]. However, due to time constraints and the limited number of trained staff in hospitals, MR cannot be performed in all patients. To optimize MR efficiency considering the available human resources, strategies have thus been implemented to identify patients who would be most likely to benefit from MR. These strategies especially focus on elderly patients due to their frailty, to their frequent polymedication, and to the resulting specific risk of adverse drug reactions they present [4,5]. This targetting is additionally justified by the lack of treatment knowledge and potential cognitive disorders elderly patients can have and which advocates for a greater control of these patients' medications [6]. The prioritization of elderly patients that consequently exist in guidelines focussing on MR however leads not to consider the potential needs of younger adults despite this population is affected by serious adverse drug reactions (ADRs) and could potentially benefit from such interventions. In the same context of limited human resources allocated to MR, exploring which strategies could allow targeting non-elderly adults who would be most likely to benefit from MR-induced treatment changes appears necessary. The present study aimed at assessing whether a MR prioritization strategy based on the identification of high-risk medication at patients' admission treatment could be of interest in hospitalised non-elderly adults.

# Methods

# **Setting and participants**

This prospective study was conducted between July and September 2017 in an internal medicine unit of the Bordeaux teaching hospital. Patients admitted to the unit include individuals with vascular diseases, systemic diseases, infectious diseases, cancer, and other medical conditions requiring hospitalization. All patients admitted in the unit during the study period, aged between 16 and 74 years, not admitted for palliative care, and taking at least two long-term treatments at admission were considered eligible.

#### Medication reconciliation and medication review

Medication reconciliation is the responsibility of the pharmacist, and includes a step of medication review under physician and pharmacist responsibility [7]. All eligible patients who consented to participate were enrolled by the pharmacist in a MR process comprising three different steps. First, 24 to 48 hours after admission, all the information relating to a patient's usual medications were collected in order to identify all of the patients' ongoing drug treatments and their conditions of use. To this end, a treatment report was constituted for each patient using information that needed to be obtained from three different sources (e.g., patient, patient's general practitioner or other practitioner, patient's relatives, patient's pharmacist, etc...). No data about the repartition of the sources used was recorded in this study. The report was compared to prescriptions recorded at the time of admission in order to identify potential discrepancies. Second, during the hospital stay, a medication review was performed by physician and pharmacist for all ongoing treatments. Further to this assessment, a pharmacist and a physician optimized the patient's drug treatments if needed, which may or may not have led to treatment change(s). Third, on discharge, the consistency between the discharge-prescription given to the patient and the decisions taken regarding her/his treatment during hospitalisation was examined; MR-induced treatment changes were performed when discrepancies were identified.

# **Data collection**

On admission, information on gender, age, ongoing medications (molecule and number) prior to admission, and patient's admission pattern and the context before hospitalization in internal medicine unit were collected. During hospitalization, we completed these by identifying all the professionals contributing to the out-hospital health management of the admitted patients; these were later contacted to complete and confirm information on ongoing drug treatments (type, dosage, indication). The patient's knowledge of her/his treatment was evaluated for each medication on an internal scale of 0 (null) to 4 (excellent) [see appendix 1]. This scale covers four knowledge-related criteria: e.g., medication (commercial name or molecule), dose regimen, medical indication and the main adverse reactions. For therapeutic indications and adverse reactions, an answer mentioning the target organ but not the exact indication was considered acceptable. Only a global score was presented in the results. During hospitalisation, changes in treatment that occurred from admission to discharge and related to the MR procedure, were recorded for all patients. Finally, the assessments of the clinical importance of the changes performed, as evaluated by the prescriber and as evaluated by the pharmacist, were collected. The physician's assessment of the clinical importance was based on her/his knowledge of the patient comorbidities, current reason for hospitalisation, and therapeutic objective. The pharmacist's assessment was performed using a standardized method (REMED [revue des erreurs liées aux médicaments et dispositifs médicaux associés]). The REMED method was developed by the French Society of Clinical Pharmacy (SFPC) to improve quality of care and to prevent medication-related adverse events, and is referenced by the French Haute autorité de santé (HAS). It allows assessing the impact of MR procedures according to the risk conveyed by the medication errors they allow preventing and proposes three levels of clinical importance for the MR-induced treatment changes: minor, clinically significant, major [8]. To allow assessing the consistency of the assessments performed by clinicians and pharmacists, a similar possibility of classification was proposed to clinicians, event they did not use the REMED tool.

Prioritization strategy: definition and identification of at-risk patients

We postulated that patients using medications frequently involved in the occurrence of serious adverse drug reactions (SADRs) could present with a higher risk of medication errors leading to adverse clinical consequences. More specifically, to target a potentially preventable risk, we considered that focusing on medication that are most involved in the occurrence of such SADRs due to misuse or overdose in patients aged between 16 and 74 years could be particularly relevant. Using information from a report published for the administrative area of Bordeaux concerning SADR data reported to the French network of Regional Pharmacovigilance Centres [9,10], all medications involved in at least 5% of SADRs occurring in situations of misuse or overdose were identified. These were qualified as high-risk medications for our study; they included antithrombotic agents, analgesics, antipsychotics, and a list of cardiac therapies (see appendix 2). Approach based on high-risk medication already proved its effectiveness in pharmaceutical validation of medical prescriptions [11]. Based on this list, we classified patients included in the study into two groups: that of patients admitted with ongoing treatment with at least one high-risk medication ("high-risk medication group", HRM group), and that of patients not admitted with such ongoing treatment (non-HRM group).

#### Assessment of the patient prioritization strategy

To evaluate the potential interest of the proposed prioritisation strategy, we compared between the HRM group and the non-HRM group the proportion of patient with at least one MR-induced treatment changes, the mean number of MR-induced treatment changes per patient and the proportion of clinically important MR-induced treatment changes (*e.g.* clinically significant or major).

# Statistical analysis

Baseline patients' characteristics and ongoing medication in both groups were described in terms of median and interquartile ranges (IQR) for quantitative variables, and numbers and proportions for qualitative ones. Treatment changes were described for the distribution of the reasons for changes and for the clinical importance as assessed by the clinician and the pharmacist; these categorical variables were also described using numbers and proportions. All variables were compared between groups using the Pearson's chi-square test or Fisher exact test for categorical variables and the Student t-test for continuous ones. All reported p-values are two tailed, and we considered p <0.05 to be statistically significant. Finally, the agreement between physicians and pharmacists assessments of the clinical importance of the treatment changes performed was assessed using the kappa ( $\kappa$ ) statistics [12]. All analyses were performed with SAS® software (SAS Institute, version 9.4, North Carolina, USA).

#### Results

A total of 211 patients were admitted to the internal medicine unit, of whom 92 met the study inclusion criteria; none of these refused to participate (Fig. 1). According to the nature of the treatment at admission, 46 patients were classified as having high-risk medication and constituted the HRM group (median age 66 years, IQR 58-70; 25 men, 21 women); the other 46 constituted the non-HRM group (median age 54 years, IQR 47-64; 22 men, 24 women; Table 1). HRM patients mainly had one high risk treatment (n = 33), and 2 high risk treatment (n = 13). Patients with more than two high risk treatment were scarce (3 high risk treatment n = 6; 4 high risk treatment n = 2).

Patients in both groups were mainly admitted through the emergency department or from home in context of scheduled hospitalisation. The remaining patients were referred to the department after a stay in the intensive care unit, or were patients for whom no information on admission was available (Table 1). Study patients were for the most part autonomous in managing their medications, reporting that they had no support from a health care professional at home. However, among the main differences found between the two groups, patients included in the HRM group had less knowledge of their treatment and were taking more medication (Table 1).

Among the total of 88 MR-induced treatment changes performed during the study period, 78.4% was performed in the HRM group. On average, among the 46 HRM patients, 37% had at least one change of treatment compared to 8.7% of the non-HRM ones (p = 0.001). The mean number of changes performed per patient at admission was also significantly higher in the HRM group than in the non-HRM one (1.0, 95%CI [0.4-1.6] *vs.* 0.17, 95%CI [0-0.4]; p = 0.01). For MR-induced treatment changes performed during hospitalization and upon hospital discharge, no significant difference was found between the two groups (Table 2). For the HRM group, high-risk medication on admission was mostly antithrombotics (52.2%), followed by antipsychotics, analgesics and cardiac therapies. Among the 69 MR-induced treatment changes, antipsychotics were the most widely represented class of medication (15.9%; Table 3). Reasons for change were mostly represented by medication omission and dose regimen errors (Table 4).

For the HRM group, 43.5% of MR-induced treatment changes were assessed as clinically major at least once by pharmacists or clinicians (Table 5). Among the high-risk patients, medication classes involved in major MR-induced treatment changes were antithrombotics and antipsychotics with 10% each, followed by cardiac therapies, antidiabetics, and anti-acid therapies (Table 3). Among MR-induced treatment changes performed in non-HRM patients, only 31.6% were assessed at least once by pharmacists or clinicians as clinically major (Table 5); they did not concern any specific drug class.

The physicians considered that 24.6% of the treatment changes performed after MR were of major clinical importance in HRM patients, compared to 15.8% in the non-HRM ones. In contrast, there was less difference in the pharmacist's assessments concerning major MR-induced treatment changes with 29% assessed in the HRM patients, compared to 26,3% in the non-HRM ones. The clinical impact assessments of MR-induced treatment changes performed by clinicians and pharmacists were consistent in 37.5% of cases, revealing a poor agreement regarding treatment changes performed in non-HRM patients and a very poor one for changes performed in HRM patients (Table 5).

#### **Discussion**

Based on the risk level of drugs prescribed on admission, our study proposes a simple and seemingly efficient approach for the prioritization of MR in hospitalised non-elderly adults. Indeed, among all patients included in our study, those taking high-risk medication at admission had a 3 to 4-fold higher rate of MR-induced treatment changes than those without such medications, these being additionally more likely to be considered clinically significant or major. Overall, the characteristics of HRM patients consistently supported the hypothesis of an efficient identification of patients at higher risk of medication error and medication significant error, as they appeared older than non-HRM patients; age being known risk factor in medication error [13]. Indeed, targeted HRM-patients allow better consideration of patients with a considerable high burden of diseases than non HRM-patients, because high-risk medications are a surrogate of comorbidities. Interestingly, HRM-patients were found to have poorer knowledge of their treatment and so were less able to ask for corrections in the event of potential medication errors, which could explain at least partly why they were more likely to present with medication errors, and more generally why their treatment could be responsible for high level of ADRs. A systematic review has shown that patient and family engagement can reduce ADRs [14]. Thus, knowing more about their treatment appears to be a key factor in patients' medication errors, and those taking highrisk medication need more information about their medication. Tools to target patients who may be less aware of some of the aims or pattern of their treatments would be of specific interest in helping prioritize medication reconciliation. This point could be an indirect outcome of the approach we propose.

The most frequent MR-induced treatment changes consisted in completing patients' treatment with medications she/he had not mentioned when she/he was admitted. The second most frequent changes consisted in correcting dose regimen error; this was observed similarly in both HRM and non-HRM patients. Overall, even if MR-induced treatment changes were not all considered clinically significant or major, these results confirm the importance of the loss of information at the time of hospital admission. Several studies have focused on solutions to improve communication between care structures [15,16], including the computerization and sharing of information through electronic heath information exchange systems. The accessibility to the shared pharmaceutical file (DP) would have made it easier and more reliable to collect the patient's list of usual treatments, however the material required to read it was not available in the department at the time of the study [17].

Both the frequency and the proportion of clinically significant or major MR-induced treatment changes were found to be much higher in HRM patients than in non-HRM ones, underlining the potential efficiency of this approach to identify patients who will be most likely to benefit from MR. However, the consistency was low between the clinical importance of the MR-induced treatment changes as assessed by clinicians or by pharmacists specially to distinguish significant and minor interventions. Clinicians tend to overestimate minor interventions as assessed according REMED method. Assessing the clinical importance or impact of MR-induced treatment changes is highly complex and involves both objective parameters, such as prescription recommendations (contraindications, interactions, overdoses, etc.), as well as subjective parameters directly linked to clinical contact with the patient. The observed disagreement could theoretically find two explanations: either the overall clinical importance was overestimated by clinicians, either it was underestimated by pharmacists. The first hypothesis could be supported by the fact that the evaluation of MR-induced treatment changes by clinician could not rely on a standardized tool, which could potentially inflate the rating when taking into account the patient's characteristics. Conversely, the structure of the REMED tool could at least partly explain the lower rating of pharmacists, the influence of treatment characteristics and nature being of primary importance for the final rating while patients' characteristics are less considered. Owing to the importance of the disagreement, we believe further research should be conducted regarding the assessment of the clinical importance of treatment changes. The REMED method, which has the advantage of framing impact assessment using several criteria, is not recognized as a Gold Standard to date; it would certainly need further work with physicians to understand the reasons for the discrepancies we observed and to allow developing a version that would be both acceptable for physcians and pharmacists in a clinical setting.

Our study presents with several limitations. The 75-year-old threshold is debateable; it was arbitrarily set according to the general definition of elderly patients owing to age. This however allowed considering in non-elderly patients subjects aged 65 to 74 who were not targeted by existing MR actions to date despite this period of ageing is usually considered as a transition period in terms of autonomy and frailty [18]. Finally, considering patients aged under 75 and targeting patients according to their potentially HRM could allow identifying indirectly patients who would be considered as elderly owing to their health conditions and disregarding age, as currently recommended by geriatric societies. In this perspective, testing the approach we propose in patients aged 75 and older could also be of interest to study whether it could help better identifying patients at risk that thresholds only based on age which is now considered as a limited marker of frailty [19]. The two medication classes most concerned by MR-

induced treatment changes were antipsychotics and antithrombotics, which was consistent with other studies [20,21]. If these results corroborated our hypothesis postulating that targeting medication known to be responsible for SADRs, misuse or overdose would be effective in identifying patients with a greater need for medication reconciliation, our study could however present with some limitations in terms of generalizability. Indeed, the list of drugs we used to define HRM was established on the basis of a report identifying the drugs most frequently involved in SADRs in the geographical areas covered by the hospital. The extent to which this list correlates with other geographical areas and other hospital settings remains uncertain. Additionally, the study was performed within a single internal medicine unit. Even if such units are supposed to host any kind of patient and to constitute, in one way, the inhospital extension of general primary care, it is most likely that the patients we studied were not fully representative of all hospitalised non-elderly patients, and neither the drugs they took. However, the principle of focussing on drugs identified as related to a high risk of adverse effects should make this approach easily adaptable to most settings. The only situation in which such approach would indeed appear fully inadequate is that of an hospital or unit in which a proactive MR process is already in place [22]. Finally, another limitation is that relating to an initial misclassification of patients. It cannot be excluded, theoretically, that a patient with HRM would have been ignored at admission, which would have led to classify her/him wrongly in the non-HRM group. If this did not happen in our study, this could of course occur in practice. Furthermore, some information may be imprecise, in particular the level of knowledge of the patient, which has been assessed from an internal scale not validated or used in other studies. This scale has the advantage of estimating through four simple questions the level of knowledge of the treatment by the patient, but the few criteria used do not allow precise estimation.

Our study conversely present with some important strengths. First the list used to define HRM was based on a study performed in the specific geographic area of the Bordeaux teaching hospital, ensuring that it was established from adverse drug reactions observed in our study population source. Second, the study was conducted prospectively allowing to perform an ad-hoc collection of data and training of the participating clinicians and pharmacists. Third, patient treatment data were collected using standardized tools and complementary sources which allowed observing no misclassification for patients regarding HRM status. Finally, the considering that all non-elderly patients were eligible for the study and that none refused to participate allows considering our study sample should be generally representative of patients admitted to internal medicine unit.

#### Conclusion

In this study, we assessed the performances of a simple approach for the prioritization of non-elderly patients who would benefit from medication reconciliation. The strategy based on the identification of high-risk medications, defined according to their importance in terms of occurrence of adverse drug reactions, showed with interesting results both in terms of induced medication changes and clinically important induced medication changes. In a context where human resources are limited to perform medication reconciliation, such pharmacovigilance-driven approach, that can theoretically be easily adapted to most settings, thus appears promising to identify, patients at high risk for medication errors in case of hospitalisation and to prevent SADRs related to these errors.

#### **Ethics approval**

This study was approved by ethics committee (CE-GP-2021-02).

## **Disclosure of interests**

FB has served as a speaker for BMS, Gilead, MSD, and ViiV Healthcare, a consultant for Pierre Fabre and ViiV Healthcare, and has received research funding from Gilead and Janssen.

FX has served as a speaker for Gilead, MSD and Abbvie.

AP is the coordinator of the French DRUGS-SAFE (DRUGS Systematized Assessment in real-liFe Environment) national platform of pharmacoepidemiology. This national platform is subsidized by the ANSM. This work is not part of the DRUGS-SAFE research program (www.drugssafe.fr).

JP, AG, ML, NB and DB have declared no conflicts of interest related to this work.

The authors have no conflict of interest related to this work to declare.

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# **Tables**

**Table 1**. General data in the high-risk medication (HRM) group and the non-high-risk medication (non-HRM) group

Characteristics, n (%)	Non-high-risk medication	High-risk medication	P
	(non-HRM) Group,	(HRM) Group,	
	N = 46	N = 46	
Age, median (IQR)	54 (47-64)	66 (58-70)	0.0027
Gender			0.5315
Male	22 (47.8)	25 (54.3)	
Female	24 (52.2)	21 (45.7)	
Origin			0.4505
Emergency	22 (47.8)	22 (47.8)	
Home	20 (43.5)	16 (34.8)	
Intensive care unit	1 (2.2)	5 (10.9)	
Other	3 (6.7)	3 (6.5)	
Knowledge of treatment			0.0956
Excellent	13 (28.3)	4 (8.7)	
Good	14 (30.4)	21 (45.7)	
Basic	12 (26.1)	14 (30.4)	
None	7 (15.2)	7 (15.2)	
No health professional home inter-	38 (82.6)	34 (73.9)	0.3120
vention			
Prescription on admission			< 0.0001
Number of medications,	4.5 (3-8)	9 (7-11)	
median (IQR)			

Table 2. Medication reconciliation-induced treatment changes in patients

Characteristics, n (%)	Non-high-risk medication (non-	High-risk medication (HRM)	P	
	HRM) group,	group,		
N. de (MD: de	N = 46	N = 46		
Number of MR-induced treatment changes, (mean per				
patient, [95% CI]*)				
Admission	0.17 [-0.03-0.37]	1.00 [0.38-1.62]	0.0139	
Hospitalization	0.07 [-0.01-0.14]	0.26 [0.04-0.48]	0.0963	
Discharge	0.17 [0.04-0.30]	0.26 [0.07-0.44]	0.4354	
Number of patients with at least 1 MR-induced treatment changes	4 (8.7)	17 (37.0)	0.0012	
treatment changes				

95% CI: 95% confidence interval

Table 3. Medication implicated in medication reconciliation-induced treatment changes

Medication class	Repartition of	Proportion of risky medication	Proportion of risky	
	medication risk among	implicated	medication implicated in	
	drugs prescribed on	in MR-induced treatment	major MR-induced	
	admission, $n = 67$	changes, $n = 69$	treatment changes assessed	
	n (%)	n (%)	by the pharmacist among	
			the HRM group, $n = 30$	
			n (%)	
Antithrombotic	35 (52.2)	7 (10.1)	3 (10.0)	
Antipsychotic	15 (22.4)	11 (15.9)	3 (10.0)	
Analgesic	13 (19.4)	5 (7.2)	0 (0)	
Cardiac therapy	4 (5.8)	3 (4.3)	2 (6.7)	

Table 4. Type of error involved in MR-induced treatment changes

Characteristics, n (%)	MR-induced treatment changes in the non high-risk medication (non-HRM) Group, n	MR-induced treat- ment changes in the high-risk medication (HRM) Group, n =	P
	= 19	69	
Reason for changes			0.1911
Omission	5 (26.3)	34 (49.3)	
Dose regimen error	4 (21.1)	13 (18.8)	
Dose error	1 (5.3)	5 (7.3)	
Addition	3 (15.8)	5 (7.3)	
History of adverse reaction	1 (5.3)	4 (5.8)	
Other	5 (26.3)	8 (11.6)	

 Table 5. Assessment of MR-induced treatment changes

Characteristics	Physician's charac-	Pharmacist's char-	Consistent assessments	Chance-corrected	
	terisation	acterisation	n (%)	agreement analysis	
	n (%)	n (%)		κ[95% CI]	
non high-risk medi-				0.27 [-0.05; 0.59]	
cation (non-HRM)					
Group					
Minor	8 (42.1)	11 (57.9)	6 (31.6)		
Significant	8 (42.1)	3 (15.8)	2 (10.5)		
Major	3 (15.8)	5 (26.3)	2 (10.5)		
Total of MR-	19 (100)	19 (100)			
induced treatment					
changes					
High-risk medica-				0.04 [-0.12; 0.19]	
tion (HRM) Group					
Minor	16 (23.2)	32 (46.4)	11 (15.9)		
Significant	36 (52.2)	17 (24.6)	5 (7.2)		
Major	17 (24.6)	20 (29.0)	7 (10.1)		
Total of MR-	69 (100)	69 (100)			
induced treatment					
changes					
Total of MR-induced	88 (100)	88 (100)			
treatment changes					

95% CI: 95% confidence interval

Figure (legend)

Figure 1. Study flowchart

Appendix (legends)

Appendix 1. Evaluation score of patients' knowledge of treatment

**Appendix 2**. At-risk medication list

