The clinical impact of medication reconciliation on admission to a French hospital: a prospective observational study

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Received 8 July 2015

Revised 6 November 2015

Accepted 11 November 2015

Published Online First

16 December 2015

ABSTRACT

Objective This study was designed to assess the clinical impact of medication reconciliation using two criteria: the number of inpatients who had experienced at least one medication error; the severity of the potential harm associated with these detected errors.

Method The study was a prospective observational one. The eligible population included patients aged 65 and over subjected to medication reconciliation at admission. The potential severity of medication errors was evaluated independently by the physician in charge of the patient and by the pharmacist involved in the medication reconciliation process. Severity assessment took account of the drug(s) involved in the error, the type of medication error, and the patient's clinical and biological data.

Results From January 2011 to September 2012, 1799 medication errors were recorded among the 1670 patients subjected to medication reconciliation who were hospitalised from the emergency department. At least one medication error occurred for 744 (44.6%) of these patients. There were 87 medication errors associated with potentially major severity (5.6%). These concerned 67 patients (4.2%). The most prevalent error was omission. Cardiovascular and anticoagulant drugs were the drugs most frequently involved in these serious medication errors. Arrhythmia, haemorrhage, thrombosis, hyperglycaemia and hypoglycaemia were identified as the most likely harms that could have occurred.

Conclusions The detection of cases of serious potential harm shows the clinical impact of medication reconciliation. It would be interesting to perform a multicentred assessment using indicators such as the number of inpatients experiencing at least one serious medication error. This could help to promote medication reconciliation as essential for patient safety.

INTRODUCTION

In France, the SFPC (Société française de pharmacie clinique) defines medication errors (MEs) as any deviation from ordinary standards of care appropriate at a particular time in the overall management of patient medication. An ME is the unintentional omission or commission of an act relating to a drug that can generate a risk or an adverse drug event for the patient. By definition, an ME is preventable because it mirrors what should have been done and was not in the course of the management of a patient's medication.¹ This definition was agreed in 2009 by the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM). It

has been used since then by French healthcare professionals. In the USA, an ME is defined more simply by the National Coordinating Council for Medication Error Reporting and Prevention as any preventable events that may cause or lead to inappropriate medication use or patient harm.² These definitions are similar in meaning. MEs are the most common type of error affecting patient safety in hospitals³ and they occur most often at transfer points in the course of care—admission, transfer between hospital units, discharge.⁴

The High 5s Project was launched by the WHO in 2006 to address current major concerns about patient safety around the world. Medication reconciliation is part of the project and addresses the prevention of MEs at points of transition in the patient care process.⁵ French healthcare facilities have increasingly implemented medication reconciliation, and there are several papers on this subject.^{6–10} However, its clinical impact has not been sufficiently assessed in France.¹⁰

The aim of this study was to explore the clinical impact of medication reconciliation at Lunéville Hospital. The objectives were to assess the number of inpatients who had experienced at least one ME and the severity of potential harm associated with these MEs detected by medication reconciliation.

METHODS

Lunéville Hospital is a public health institution with 420 beds serving a population of 90 000.

The clinical impact of medication reconciliation was analysed in a prospective, observational study that ran from January 2011 to September 2012. The wards involved were medical, surgical and intensive care. Patients from the maternity department, the very-short-term care and the long-term care wards, and the two long-stay units for dependent elderly were excluded.

The medication reconciliation process has been implemented since 2009 in Lunéville Hospital, and its performance has been described in a recent publication.¹¹ It involves patients aged 65 years and over admitted through the emergency department. The process starts with an active search of the complete home medication list as soon as the patient is hospitalised. All the data derived from the medication reconciliation are recorded on a specific sheet dedicated to this process. The pharmacist creates the list after analysis of up to 14 sources of information (electronic medical file, community pharmacist, general practitioner (GP), patient, letter from GP, letter to GP, patient's prescription,

To cite: Dufay E, Morice S, Dony A, et al. *Eur J Hosp Pharm* 2016;**23**:207–212.

previous medical record, interview with family, drug packaging, nursing home, letter from consultant, home nurse, pharmaceutical record).¹² This is carried out as quickly as possible, with no deadline. The list is compared with the admission prescription drafted in the medical or surgical wards. The pharmacist identifies any discrepancies and contacts the prescribers to reconcile them. A physician characterises the discrepancies as intentional or not. Any unintentional error, recorded as an ME, is immediately corrected and a new prescription is issued. The medication reconciliation sheets are signed by the pharmacist. When they have been completed by a physician, they are archived in the patient's medical file.

MEs detected in the setting of this medication reconciliation process were included in the study. Healthcare practitioners used the medication reconciliation form formalised under Open Office, where MEs are also recorded. They also completed a patient file manually with the cause of hospitalisation, medical history and biological data. The severity of the potential consequences of the ME was assessed immediately after its detection and correction, as in the usual, ongoing medication reconciliation process. The physician in charge of the patient and the pharmacist assessed the MEs independently in a blinded manner. Thirteen physicians and one senior pharmacist were involved in this study. Before the beginning of the study, they received training to familiarise themselves with the method of scoring potential severity. The training included the description of the method and an example. Potential severity was explored with the following questions: 'What would have been the consequences of the ME for the patient if it had not been detected?'; 'What could be the worst consequence for the patient?'. The time after which any potential harm might have occurred was not defined: it could occur during or after the hospitalisation. This question also assumed that no medical or pharmaceutical interventions affecting the therapeutic management of the patient had occurred to correct the ME.

The severity of the potential consequences of MEs considered the drug(s) involved in the ME, the type of ME, and the

patient's clinical and biological data and was determined using the SFPC tool for the 'Characterisation of medication errors' (table 1).^{13–15} Additional information on the characterisation of MEs can be found on the SFPC website.¹⁶

Severity was assessed in two stages on a five-category scale. First, the health professionals were asked to assess severity according to the first three levels of the scale: 'minor', 'significant' and 'serious'. The 'serious' category is subdivided into three levels (giving five in all): 'major', 'critical' and 'catastrophic' (table 1). The agreement between the physician in charge of the patient and the pharmacist was first assessed on the first three levels of the scale. In a second step, they assessed the severity of the potential harm for which they had agreed on 'serious' status using the three sub-categories of 'serious'. Agreement was then measured a second time.

In the case of disagreement between the physician and pharmacist, the MEs were excluded from the dataset.

The anatomical therapeutic chemical (ATC) (WHO Collaborating Centre for Drug Statistics Methodology) classification of the drugs, the types of ME, and the severity were collected under Open Office by the pharmaceutical team (one pharmacist, one pharmacy resident and four pharmacy students). ME characteristics and study results were calculated using proportions and means with SD and ranges. The χ^2 test was applied for comparison when needed. Cohen's κ test was used to determine the agreement between physician and pharmacist using Stata statistical software (V10.1) with a chosen threshold of 0.8.¹⁷

RESULTS

Over the 21 months of the study, 1810 patients were eligible for inclusion. Among these patients, 1670 (92.3%) underwent the medication reconciliation process. The mean age of the patients included was 81.8 ± 7.7 years (range 65–106). Six drugs or more were prescribed for regular use before admission to hospital of 1198 (71.7%) of the patients. A mean rate of 7.6 ± 3.6 drugs was prescribed on the first day of hospitalisation after

Table 1 The three criteria used to characterise MEs by the SFPC

1st	Drug(s) involved in the ME ATC classes	
2nd	Type of ME	
	Wrong patient	–
	Drug omission	–
	Wrong drug	Including inappropriate choice of medication according to medicine therapy, inappropriate administration protocols, therapeutic redundancy or duplication, inappropriate additional medication, contraindication, inappropriate drug presentation, known allergy, outdated or damaged medications, etc...
	Wrong dosage	
	Dose too high	Dosage, frequency, dose interval, regimen, concentration, volume, infusion rate, rate of administration, rate of topical application, etc...involving a higher or lower dose than the correct dosage
	Dose too low	
	Wrong administration route	Route, length of infusion, administration technique, etc...
	Wrong moment	–
	Wrong duration	–
3rd	Severity of the consequences of the ME	
	Minor	MEs with no harm to the patient
	Significant	MEs requiring monitoring but no harm to the patient
	Serious	
	Major	MEs with temporary harm to the patient: additional treatment or intervention required, transfer or hospitalisation or prolongation of hospitalisation
	Critical	MEs with permanent harm to the patient
	Catastrophic	MEs that are life-threatening or lead to the death of the patient

ATC, anatomical therapeutic chemical; ME, medication error; SFPC, Société française de pharmacie clinique.

medication reconciliation. Among the 1670 patients subjected to medication reconciliation, at least one ME occurred for 744 subjects (44.6%). The total number of MEs that were detected and corrected was 1799, with a median of 2 (range 1–9). The 122 MEs that were not characterised (one practitioner unavailable) were excluded from the inter-rater assessment (figure 1).

The results for the evaluation of the severity of 1677 MEs are presented in table 2. The physicians and pharmacist characterised 1562 MEs out of 1677 in the same way, giving an agreement rate of 93.1%. Cohen's κ coefficient was 0.84. The agreement between physician and pharmacist in this first evaluation was very high, since 0.8 is considered excellent agreement and therefore confirms the homogeneity of the assessments. Indeed, a discrepancy between a minor assessment and a serious assessment was observed for only 1.1% of the MEs. This value strengthens the conclusion.

The ME consequences characterised as 'serious' by both physicians and pharmacist amounted to 5.2% (87/1677) of all errors analysed. In the second stage of severity characterisation, the physicians and pharmacist classified all errors as major (none as critical or catastrophic). This gave 87 MEs with potentially major consequences per 44 870 hospitalisation days (HDs) (1.9 ME/1000 HDs). Sixty-seven patients out of the 1614 with reconciled medication (4.2%) were exposed to at least one serious ME.

These 87 MEs were analysed on the basis of ATC class and type, with only the MEs characterised in the same way by physician and pharmacist being retained.

Figure 2 shows the distribution across ATC classes. Cardiovascular drugs (class C), especially diuretics and β blockers, were related to 36.8% (32/87) of the 'major' MEs. Drugs affecting blood and haematopoietic organs (class B; vitamin K antagonists and platelet aggregation inhibitors) were the next

Table 2 Severity of the potential consequences of 1677 medication errors

	Physicians				Total
	Severity	Minor	Significant	Serious	
Pharmacist	Minor	1160	16	3	1179
	Significant	64	315	6	385
	Serious	15	11	87	113
	Total	1239	342	96	1677

most likely to be related to a major ME. Drugs for the sensory organs (class S) were next, with antiglaucoma eye drops. Figure 2 also shows the distribution of ME types. Among 'major' MEs, 71.3% (62/87) were due to omissions of medication. The percentages of MEs related to wrong dosage, wrong drug and wrong route of administration were, respectively, 17.2%, 10.3% and 1.1%. Concerning the wrong dosage, the percentages were 6.9% for a dose that was too high and 10.3% for a dose that was too low. Omissions relating to cardiovascular drugs, antithrombotic agents or antiglaucoma eye drops amounted to more than a half of the serious MEs (55.2%). The potential harms were arrhythmia, haemorrhage, thrombosis, hyperglycaemia and hypoglycaemia (table 3).

DISCUSSION

Assessment of risk

In this study, the SFPC scale was used to characterise ME consequences and potential severity.^{15 16} This tool was adapted from the generic risk severity measure promoted by the Haute Autorité de Santé (HAS) in France, in its guidelines 'La sécurité

Figure 1 Flow diagram of patients and medication errors.

Figure 2 Anatomical therapeutic chemical (ATC) classes and types of the 87 serious medication errors (MEs).

Table 3 Clinical impact of the 87 serious MEs

ME ATC class	ME type			
	Omission	Wrong drug	Wrong dosage	Other
C, Cardiovascular system	22	4	6	0
B, Blood and blood-forming organs	13	1	3	0
S, Sensory organs	13	0	0	0
A, Digestive system and metabolism	6	0	2	0
Other	8	4	4	1

Most common MEs: 13 omissions of eye drops for glaucoma; 9 omissions of acetylsalicylic acid; 5 omissions of insulin; 5 omissions of ACE inhibitor or angiotensin II receptor antagonist; 5 omissions of β blockers; 4 omissions of diuretics; 4 omissions of vitamin K antagonist; 2 doses of β blockers too high; 2 doses of β blockers too low; 2 doses of vitamin K antagonist too high; 2 doses of insulin too high; 2 doses of antiepileptics too low; 2 omissions of calcium channel blocker; 2 omissions of nitrate patches; 2 omissions of digoxin; 2 omissions of gout drug; 2 additions of psycholeptics.

Example: Mr Rob, 86 years old, was hospitalised for poor general condition through the emergency department. The patient had dementia, stroke and fast atrial fibrillation. The general practitioner's letter did not specify the patient's medication regimen, so the resident used the last prescription of a previous hospitalisation. The omission of the oral anticoagulant, fluindione (Previscan 20 mg tablet), was detected through medication reconciliation. The regimen was 1/4 tablet once a day. For 2 days, the patient did not receive the drug, which was not mentioned on the last prescription. During the assessment, the physician and pharmacist agreed that there was a risk of thromboembolism and likelihood of stroke recurrence if the ME was not corrected.

ATC, anatomical therapeutic chemical; ME, medication error.

des patients et la mise en œuvre la gestion des risques associés aux soins en établissement de santé' (Patient safety and care-related risk management in health facilities).¹⁸ The five severity categories (minor, significant, major, critical and catastrophic) are applied to the particular situations of the different MEs, with details of the impact of MEs adapted from the taxonomy of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).¹⁹ To further increase objectivity, severity was evaluated independently by a physician and a pharmacist. Because of the very high κ value (0.84) and the low percentage (1.1%) discrepancy in 'minor/serious' between the two raters, we can conclude that agreement was high and the evaluation of the potential severity of MEs was very good. These results support the use of the SFPC scale by healthcare professionals and raise awareness of the risk associated with an inadequate reconciliation medication process.

Interest in a universal tool to characterise MEs

The clinical impact of medication reconciliation has not been sufficiently assessed in France. However, a three-category scale, adapted from the harm-level taxonomy of NCC MERP, was used to rate MEs in the Quélenec study.¹⁰ Certain parallels can therefore be drawn with our study: category C is minor severity, category D is significant severity, and grouped categories E and F are major severity. According to the Quélenec study, 27.2% (47/173) of the detected MEs in the severity category were classified at least as significant, versus 24.0% (402/1677) in our study ($p=0.35$). The most common type of error was omission: 87.9% versus 53.5% (829/1549) in our study. These

percentages are, however, not comparable because the types of ME are defined differently and are therefore differently distributed.

The clinical impact of medication reconciliation has been more widely studied at international level.^{20–21} Kwan *et al*²² assessed the potential effect in terms of ‘unlikely’, ‘possible’ or ‘probable’ patient discomfort and/or clinical deterioration. This amounts to assessing frequency rather than severity. According to Cornish *et al*,²³ 5.7% of MEs had the potential to cause severe discomfort or clinical deterioration. MEs were classified according to their potential to cause harm using a three-category scale: ‘unlikely’, ‘moderate’ and ‘severe’. The terms were not defined but illustrated by examples. Pippins *et al*²⁴ defined ME types (not the same as ours) using a confidence scale and three categories of potential severity termed ‘significant’, ‘serious’ and ‘life-threatening’. The last two categories have similarities to our scale. Error severity was assessed in a blinded manner by a team of physicians, and 6.3% of the potential adverse drug events were considered serious. In the study of Gleason *et al*,²⁵ 11.7% of the MEs were rated as potentially harmful (categories E and F in NCC MERP taxonomy). Slee *et al*²⁶ considered that 17.7% of the pharmacist interventions prevented potentially serious events. In that study, medication reconciliation and assessment of patients’ need for a drug were two combined interventions by pharmacists, explaining the high percentage of potentially harmful MEs and drug-related problems.

Our results cannot be directly compared with those in the literature because the study details differed or were not sufficiently explicit, and also because ME types or severity scales were not defined in the same way. Although the results cannot be compared, a similarity can be seen: medication reconciliation is confirmed as a powerful method for detecting MEs and potentially preventing adverse drug events. In the different publications, the most common type of error found was omission linked to cardiovascular drugs and drugs affecting the blood and haematopoietic organs. However, to provide optimum care, it would be helpful if all studies adopted a common severity scale that is easy to use and leaves little room for interpretation.

Clinical impact is not enough to convince

In our study, 4.2% of patients had at least one serious ME. It should be noted that the potential harm avoided might have occurred either during hospitalisation or after the patient had returned home. Practitioners at the Lunéville Hospital are convinced that medication reconciliation at admission prevents iatrogenic illness. Understanding this is the first step to promoting medication reconciliation among healthcare professionals and implementing it at all transitions in care.

However, this is not the only effect to consider; there is an economic corollary. So far, this aspect has been assessed in the USA, where Karnon *et al*²⁷ have shown that medication reconciliation is cost-effective. A new issue has been raised combining the clinical and economic dimensions of medication reconciliation: it has been noted by Jack *et al*²⁸ that the frequency of 30-day rehospitalisation is lower among patients who have had a re-engineered hospital discharge programme that included a medication reconciliation process. In France, these advantages have not yet been demonstrated, and there is no evidence that medication reconciliation is less time-consuming than the usual procedures. As a result, reconciliation is controversial because of its apparent complexity and its mobilisation of human resources, especially among pharmaceutical professionals. In Lunéville Hospital, before the implementation of medication reconciliation, the task was performed by physicians and nurses in each

healthcare unit through which the patient moved. Because the process of establishing the medication list was not sufficiently formalised or organised by any of these health professionals, it was repeated in at least two healthcare units: the emergency department and the first hospitalisation care unit. In a previous study, we noted that only 24.1% of medication prescriptions written up in the emergency department were complete, and 81.3% in follow-up wards.¹¹ According to the study of Caglar *et al*,²⁹ only 13% of medication prescriptions were complete, and in the study of Barillet *et al*⁹ the proportion was 25%. When the medication reconciliation process is well organised and centralised by pharmacists, it appears to be time-consuming, because everything is carried out in one place, at one moment, by one person, but, overall, less time is actually required. In addition, damage that may result from the lack of communication between the different health professionals is not managed by the same professionals as those encountered during a previous hospitalisation. All these factors can help to reduce the value of medication reconciliation.

Limitations and strengths of the study

First, this study was conducted at a single hospital with no patient randomisation. Scheduled hospitalisations or hospitalisations of young patients through the emergency department were not assessed. Eligible patients were only those aged 65 or older, hospitalised through the emergency department according to the High 5s medication reconciliation standard operating protocol.

Second, the study measured potential, and not actual, harm. No consensus exists for measurement of the potential severity of MEs.³⁰ In the present study, the method was derived from that of Gleason *et al*.²⁵ However, the physician who was asked to measure the clinical impact was the one who was in charge of the patient. This could be considered a bias in the study. However, increasing the number of health professionals rating the potential impact may have led to increased variability in opinions. Despite these limitations, our results are comparable to those found in the literature.

Finally, one strength of this study is the large number of MEs characterised in comparison with other published data.^{10–24–25}

What this paper adds

What is already known on this subject

- ▶ Medication reconciliation is a powerful method for detecting medication errors.
- ▶ Medication reconciliation is a powerful method for preventing adverse drug events.
- ▶ The clinical impact of medication reconciliation is not yet clearly defined.

What this study adds

This large-scale study explores the clinical impact of medication reconciliation at a French hospital as part of the WHO’s High 5s Project to improve patient safety. The objectives were to determine:

- ▶ The number of inpatients who experienced at least one medication error at admission.
- ▶ The severity of potential harm associated with these detected medication errors.

CONCLUSION

More than 44% of the 1670 patients with reconciled medication had at least one ME; 4.2% of these had at least one ME associated with potentially major severity. Our findings suggest that medication reconciliation is essential for medication safety of patients.

Two further studies need to be performed. The first is an assessment of the clinical impact of medication reconciliation. It would be interesting to perform a multicentred assessment using indicators such as the number of inpatients with reconciled medication with at least one serious ME. The second is an economic comparison between the resources invested in medication reconciliation—not as considerable as is generally supposed—and the saving achieved. Both could help to establish medication reconciliation as essential for patient safety.

Acknowledgements The authors thank Professor Marie Claude Saux, former President of the Société Française de Pharmacie Clinique, for the research programme undertaken on the subject of medication errors and for the development of methods and tools to prevent and manage medication errors. All the authors are very grateful to Angela Swaine Verdier for help with revising the English manuscript of this article.

Methodological support From the Haute Autorité de Santé, Saint Denis, France and from OMEDIT Aquitaine—Agence régionale de santé d'Aquitaine, Bordeaux, France, managing the WHO High 5s Project in France, in which eight other facilities are involved (Centre hospitalier de Compiègne, Centre hospitalier universitaire de Grenoble, Centre hospitalier de Lunéville, Clinique de la Croix blanche de Moutier Rozeille, Centre hospitalier universitaire de Nîmes, Groupe hospitalier Nord Bichat Claude Bernard de l'assistance publique des hôpitaux de Paris, Centre hospitalier de Saint Marcellin, Centre hospitalier universitaire de Strasbourg).

Competing interests None declared.

Ethics approval The ethics board of Lunéville Hospital approved the study protocol.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The anonymous data are available, which the authors can provide on request by email.

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