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Clinically significant medication errors in surgical units detected by clinical pharmacist: A real-life study

Pierre Renaudin[1,2,3] | Annabelle Coste[1] | Yohan Audurier[1] | Julie Berbis[2] | François Canovas[3] | Laura Lohan[1,4] | Louis Dagneaux[3] | Anderson Loundou[2] | Mohamed Boucekine[2] | Maxime Villiet[1] | Cyril Breuker[1,4]

[1]Clinical Pharmacy Department, CHRU de Montpellier, Univ Montpellier, Montpellier, France

[2]EA 3279 – Centre d'Études et de Recherche sur les Services de Santé et la Qualité de Vie, Faculté de Médecine Timone, Aix-Marseille Université, Marseille, France

[3]Department of Traumatic and Orthopaedic Surgery, CHU Montpellier, Univ Montpellier, Montpellier, France

[4]Inserm, CNRS, CHRU de Montpellier, Phymedexp, Université de Montpellier, Montpellier, France

Correspondence
Cyril Breuker, Clinical Pharmacy Department, CHRU de Montpellier, Univ Montpellier. Montpellier, France.
Email: c-breuker@chu-montpellier.fr

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1 | INTRODUCTION

Medication errors (MEs) and adverse drug events (ADEs) are major public health issues in hospitals because of their consequences for patient morbidity-mortality and their economic costs. ME is defined 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 health care professional, patient, or consumer'. MEs may account for up to 28% of emergency department visits.[1] In addition, the incidence of ADEs is statistically higher in the surgical units compared with the medical departments and are particularly high in orthopaedic and trauma surgery units.[2] ADE is defined as an injury resulting from the use of a drug. Given the preventability, frequency, and potential association of MEs with adverse patient outcomes, strategies for detecting ME and preventable ADE are of utmost importance. One strategy for preventing hospital MEs and preventable ADEs is the integration of clinical pharmacists into the medical teams of the care units and the development of clinical pharmacy activities such as medication reconciliation. Consequently, the aim of our study was to evaluate the prevalence of clinically significant ME in surgical units and investigate the impact of clinical pharmacists' intervention on ME correction.

2 | MATERIALS AND METHODS

2.1 | Study design, setting and participants

This was a prospective observational study using MEs detected by pharmacist intervention (PI) over 2 months from 9 January 2017 to 3 February 2017 and between 13 February and 13 March 2018 in two units of a university hospital: an orthopaedic surgery unit and a trauma unit. PI is defined as the following 'any action taken by a pharmacist that aims to change patient management or therapy'. We included all adult patients admitted to the surgery and trauma units during the period of study, and they were followed until unit discharge. Non-inclusion criterion was patients admitted at weekends who had left hospital before Monday morning. The study period represented 4 weeks, that is, 20 working days, from Monday to Friday, during which these two care units benefited from a full-time pharmaceutical presence (two pharmacists

and four pharmacy students). This study was conducted in accordance with the Basic & Clinical Pharmacology & Toxicology policy for experimental and clinical studies.[3] Some preliminary results of this study have already been published.[4]

2.2 | ME detection

MEs were detected during the routine daily activities of the clinical pharmacist from patient inclusion to discharge from the unit. The MEs were immediately presented to the relevant health professionals upon detection. The clinical pharmacist activities, carried out as part of standard patient care, were as follows: (1) prescription review, (2) best possible medication history, (3) medication reconciliation, (4) visit to the ward, (5) therapeutic drug monitoring, and (6) management of supply as well as the stock and storage of health products. PI may therefore be intended for prescribers in relation to prescriptions or nurses in connection with the admitting procedures and for administering drugs.

2.3 | Data collection

The type of MEs and PIs were classified according to the French Society of Clinical Pharmacy criteria. For each ME, the pharmacist completed the report form, recording the date; socio-demographic, therapeutic and clinical data; drug involved; and type of admission. An ME was defined as any PI accepted by the prescriber. A PI was 'accepted' when the physician took it into account for the treatment; a PI was considered 'refused' when the prescription remained unchanged, including expressed refusal by the prescriber.

2.4 | Endpoint

The primary outcome was the occurrence of at least one clinically significant ME at any time during the in-hospital stay. The significant ME was defined by a major ME or lethal clinical impact. The clinical impact of each PI corresponding to ME was retrospectively assessed by a panel of pharmacist experts using the CLEO three-dimensional scale.[5] The clinical impact categories included harmful, null, minor, moderate, major, lethal and non-determined. Major and lethal MEs can lead to harm that causes or lengthens a hospital stay or causes permanent disability or handicap or to an accident that causes potentially intensive care or death of the patient, respectively. The clinical impacts of the MEs were evaluated by three clinical pharmacists with more than 2 years of experience in clinical pharmacy. A consensus based on the two-thirds rule was adopted to determine the ME rating. In cases where a consensus was not achieved, consultation among the three clinical pharmacists was carried out, with the aim of finding a consensus.

2.5 | Statistical analysis

Univariate analyses were performed using the Mann–Whitney test for continuous variables and χ^2 test for categorical variables.

2.6 | Ethics approval

All patients included in our study received normal clinical care. Our interventions consisted of conventional clinical pharmacy activities who were approved by the Hospital Institutional Review Board. Oral consent was obtained before inclusion in the study. The study has been registered at ClinicalTrials.gov under the number NCT03481439.

3 | RESULTS

3.1 | Patient characteristics and clinically significant ME

In total, 462 patients were included and analysed. The patients' characteristics and outcomes are reported for the patients with and without clinically significant ME in Table 1. Ninety-five (20.5%) patients presented at least one clinically significant ME. Patients with clinically significant MEs were older (68.0 ± 17.9 vs. 62.3 ± 22.0, $p < 0.01$), more often hospitalized in trauma unit (61.1% vs. 48.2%, $p < 0.05$), more affected by infection (18.9 vs. 5.7, $p < 0.001$), had higher ASA classification (ASA $\geq$ III, 40.0% vs. 24.8%, $p < 0{,}005$) and a longer length of stay (9.1 ± 7.7 vs. 5.8 ± 5.9, $p < 0.001$) (Table 1).

3.2 | Rating medication errors

Medication errors are described in Table 2. In total, 96.4% ($n = 1764$) of IP were accepted by prescribers corresponding to MEs and were evaluated. No ME had a harmful or lethal impact. A total of 217 (12.2%) MEs had no influence on the patient, 787 (43.8%) had a minor impact, 599 (33.6%) had a moderate impact, and

TABLE 1 Baseline patient characteristics and outcomes

Patient characteristics	Population		
	No clinically significant MEs ($N = 367$)	Clinically significant MEs ($N = 95$)	*p* value
Age, years	62.3 ± 22.0	68.0 ± 17.9	<0.01
Male	160 (43.6%)	48 (50.5%)	<0.05
Mean length of stay	5.8 ± 5.9	9.1 ± 7.7	<0.001
Physical status score			<0.005
I	100 (27.2%)	12 (12.6%)	
II	176 (48.0%)	45 (47.4%)	
III	73 (19.9%)	34 (35.8%)	
IV	8 (2.2%)	2 (2.1%)	
V	0 (0.0%)	0 (0.0%)	
ND	10 (2.7%)	2 (2.1%)	
Severe renal insufficiency (yes)	11 (3.0%)	5 (5.3%)	0.34
Presence of an infection (yes)	21 (5.7%)	18 (18.9%)	<0.001
Obesity[a] (yes)	24 (6.5%)	9 (11.2%)	0.24
Care units			<0.05
Orthopaedic surgery (planned hospitalization)	190 (51.8%)	37 (38.9%)	
Trauma (unplanned hospitalization)	177 (48.2%)	58 (61.1%)	
Substance addiction (yes)	3 (0.8%)	2 (2.1%)	0.27
Alcoholism[b] (yes)	22 (6.6%)	6 (7.4%)	0.81
Admission reason[c]			0.54
Total hip prosthesis	45 (16.1%)	17 (17.9%)	
Total knee prosthesis	48 (17.2%)	15 (15.8%)	
Osteosynthesis	118 (42.3%)	46 (48.4%)	
Other	68 (24.3%)	17 (17.9%)	

Note: Data are the mean ± SD, or *n* (%).
Abbreviations: ME, medication error; NA, not applicable; ND, non-determined.
[a]Fifty-two participants with missing data.
[b]Three participants with missing data.
[c]Eighty-eight participants with missing data.

159 (9.0%) had a major impact. Clinically significant MEs were mostly detected during the pharmaceutical analysis (88.7%), mainly concerned untreated indications (78.0%) and involved medication of blood and blood forming organs (56%) and anti-infectives drugs (19.5%).

4 | DISCUSSION

In the present study, surgical care pharmacists detected and corrected 1764 MEs including 159 clinically significant ME in 95 patients corresponding to 20.6% of the population. Pharmacists resolved MEs related to untreated indications, prescription assistance, subtherapeutic dosages and prescriptions without an indication. In addition, the acceptance rate of pharmacist interventions was close to 100%. Patients with MEs were older, had more unscheduled admissions, higher ASA classification, longer length of stay and more infections. Finally, clinically significant ME mostly involved high-risk medications such as blood and blood-forming organs drugs and general anti-infectives for systemic use.

Concerning our results, we found more patients with at least one clinically significant ME compared to other comparable studies.[6,7] These differences in incidence of serious MEs may be due to the profile of patients and care units. Many studies are limited because they include patients over 65 years, in different care units, use of

TABLE 2 Characteristics of pharmacist interventions and medication errors for derivation and validation cohorts

	Total ME	Clinically significant ME
Consideration of pharmacist intervention by the physician		
Accepted	1764 (96.4)	159 (100)
Refused	54 (3.0)	0 (0)
Undetermined	11 (0.6)	0 (0)
Pharmacist activities		
Pharmaceutical analysis	1318 (72.1)	141 (88.7)
Medication reconciliation	373 (20.4)	16 (10.1)
Information search	92 (5.0)	2 (1.3)
Logistics	46 (2.5)	0 (0)
Type of errors		
Untreated indication	1300 (71.1)	124 (78.0)
Subtherapeutic dosage	115 (6.3)	23 (14.5)
Supratherapeutic dosage	77 (4.2)	3 (1.9)
Non-conformity to guidelines/ contra-indication	110 (6.0)	4 (2.5)
Health product without indication	61 (3.3)	3 (1.9)
Unrealized drug monitoring	52 (2.8)	0 (0)
Improper administration	37 (2.0)	1 (0.6)
Invalid prescription	56 (3.1)	1 (0.6)
Other	19 (1.0)	0 (0)
Type of interventions		
Addition of a new drug	1318 (72.1)	123 (77.4)
Dose adjustment	168 (9.2)	20 (12.6)
Drug discontinuation	112 (6.1)	2 (1.3)
Prescription assistance	64 (3.5)	3 (1.9)
Assistance in hospital delivery	52 (2.8)	0 (0)
Drug monitoring	37 (2.0)	1 (0.6)
Change of administration route	15 (0.8)	4 (2.5)
Drug switch	30 (1.6)	5 (3.1)
Administration mode optimization	22 (1.2)	1 (0.6)
Other	11 (0.6)	0 (0)
Medication involved (ATC Classification System Level 1)	1756	159
A - Alimentary tract and metabolism	212 (11.6)	10 (6.3)
B - Blood and blood-forming organs	282 (15.4)	89 (56.0)
C - Cardiovascular system	229 (12.5)	8 (5.0)
D - Dermatologicals	11 (0.6)	0 (0)
G - Genito-urinary system and sex hormones	35 (1.9)	0 (0)
H - Systemic hormonal preparations	41 (2.2)	0 (0)
J - General anti-infectives for systemic use	151 (8.3)	31 (19.5)

(Continues)

TABLE 2 (Continued)

	Total ME	Clinically significant ME
L - Antineoplastics and immunomodulator agents	17 (0.9)	0 (0)
M - Musculo-skeletal system	19 (1.0)	0 (0)
N - Nervous system	666 (36.4)	21 (13.2)
P - Antiparasitic products, insecticides and repellents	6 (0.3)	0 (0)
R - Respiratory system	47 (2.6)	0 (0)
S - Sensory organs	30 (1.6)	0 (0)
V - Various	10 (0.5)	0 (0)
Error involved medical device	62 (3.4)	0 (0)
Error involved clinical procedure	11 (0.6)	0 (0)

Note: Data are *n* (%).
Abbreviations: ATC, Anatomical Therapeutic Chemical classification system; ME, medication error.

different definitions and terms for drug-related patient safety as described in the systematic review of Falconer et al.[8] Surgical units are known to be at risk for ME. Pharmacists have an important role in the fight against MEs and adverse drug events. This role is needed since a majority of MEs are linked to poor coordination of care and inappropriate prescribing. Several pharmacist-led interventions can be used to detect and correct MEs but very few studies evaluated all pharmaceutical interventions performed throughout the hospitalization and including the entire care management.[9] Thus, many studies evaluated only one type of pharmaceutical intervention such as medication reconciliation and that on a single clinical management issue.[10] Our results allowed to highlight that pharmaceutical analysis was the pharmaceutical activity that detected the most MEs in our surgical units. The originality of our study lies in the fact that we analysed all pharmaceutical interventions throughout the hospital stay and in all aspects of care management over two distinct periods of time in two surgical units. We need more studies that evaluate the clinical impact of having a full-time pharmacist in a care unit. Moreover, we need studies highlighting the profiles of patients at risk of clinically significant MEs in order to target pharmacists' interventions.

5 | CONCLUSION

One strategy for preventing hospital MEs and preventable ADEs is to identify high-risk patients so that physicians or pharmacists can consider the patients' level of risk when deciding on the drug surveillance strategy. The preliminary results of our study confirmed the risk of MEs in surgical units and identified variables associated with the presence of clinically significant ME. The next step in this work will be to validate our results using an independent set of patients to develop a prediction score of MEs.

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CONFLICTS OF INTEREST

All authors report no conflict of interest.

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