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Research in Social and Administrative Pharmacy

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Documentation of drug related problems and their management in community pharmacy: Data evolution over six years

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ARTICLE INFO ABSTRACT Keywords: Background: Documentation of pharmacists' activities, such as drug related problems (DRPs) management, is Documentation necessary to estimate fair remuneration but is rarely done in community pharmacies. Community pharmacy services Objective: To document and evaluate the evolution of DRPs prevalence and management over six years. Medication review Methods: Observational study carried out since 2016 in a community pharmacy. Documentation was made yearly Drug related problem for 21 days (depending on seasons, holidays and medical internship rotations) using the ClinPhADoc tool. Pharmaceutical intervention Pharmacists documented: medication, DRP type, intervention, implied partner and time for DRP management. A subanalysis was made depending on the medical rotation. Results: A total of 171 437 prescriptions were received and 6 844 (4.0%) documented with 1 550 DRPs. Most frequent DRPs were procedural (n = 506, 32.6%), dosage/posology (n = 263, 17.0%) and drug-drug interaction

frequent DRPs were procedural (n = 506, 32.6%), dosage/posology (n = 263, 17.0%) and drug-drug interaction (n = 153, 9.9%). Mean time dedicated to DRP management was 6.9 min, the longest time was for clinical DRPs (11.0 min, SD = 6.6). Most DRPs (n = 726, 44.6%) were managed by the pharmacist alone taking less working time than when involving other stakeholders (p < 0.01). Statistically significant differences were found in DRPs between the beginning and end of medical rotation (p < 0.05).

Conclusions: Documentation of DRP management allowed consistent results over the years. Patterns of DRPs can be used to develop inter-professional interventions to prevent DRPs.

1. Introduction

A Drug-Related Problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.¹ Its management involves pharmacists' activities and different partners (patients and/or other health professionals).^{2,3} Documentation of pharmacists' activities, particularly those targeting DRPs, has been recommended internationally to assess appropriately the impact on clinical outcomes.^{4,5} However, the lack of standardized documentation systems inside community pharmacies presents a major obstacle for documenting clinical activities.⁵ The existing documentation tools have been deemed incompatible with the workflow in

community pharmacies due to tools' complexity; omission of the actions taken by the pharmacist to resolve the DRP or its clinical significance.¹ Furthermore, studies that report DRPs are normally transversal or carried out during short periods of time.⁶ The World Health Organization (WHO) included as one of the three actions its Global Patient Safety Challenge⁷ "strengthening the quality of data to monitor medication-related harm; providing guidance and developing strategies, plans, and tools to ensure that the medication process has the safety of patients". As part of such initiative⁷, it is also important to evaluate DRPs during long periods of time to monitor its evolution.

Pharmacists' roles as patient care providers is growing, but remuneration for activities apart from dispensing is not consistently offered.⁸

¹ These authors contributed equally to this work.

https://doi.org/10.1016/j.sapharm.2023.07.001

Received 5 December 2022; Received in revised form 20 June 2023; Accepted 2 July 2023 Available online 4 July 2023

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In Switzerland, payment schemes for pharmacist's services related to dispensing prescription drugs remunerate activities on a fee-for-service basis⁹ that currently rely on drug validation which includes the identification, prevention and resolution of DRP such as drug-drug interactions or risk factors. In addition, documentation and consequently, their economic implications such as remuneration are rarely evaluated, particularly in the ambulatory context.^{10,11} The development of quality indicators in primary care will be closely related to future remuneration.¹² Hence, the development and evaluation of such indicators over time should be supported in community pharmacies.

Tools for documenting clinical activities related to DRPs in Swiss community pharmacies have already been developed¹³ but a simpler tool was needed to support a long-term use. For that, the Clinical Pharmacy Activities Documented (ClinPhADoc) tool has been proven reliable and acceptable in one study from 2019 but its implementation in daily practice needed evaluation.¹⁴ It includes three categories of DRPs: (i) clinical (related to efficacy or toxicity); (ii) technical (related to medication use); and (iii) procedural (related to renewals of expired prescriptions by pharmacists to ensure continuity of treatment). The present study presents a first experience to document DRPs using the ClinPhADoc tool and evaluate over six years the evolution of DRPs and pharmacists' activities to manage them.

2. Methods

2.1. Study design

Observational prospective study carried out for six years (April'2016–December'2021). Given its descriptive nature and the absence of patients' data, this study is excluded of the Swiss laws on clinical research by the Ethics Committee of Vaud (CERV-VD Req-2022-01021).

2.2. Setting

The study was undertaken in a single community pharmacy (UP, Unisanté Pharmacy).^{15–17} The UP is a community pharmacy located in a university hospital and serves an average of 28 600 prescriptions annually from patients coming mostly, but not exclusively, from the hospital (Centre Hospitalier Universitaire Vaudois) and an academic outpatient clinic (Unisanté). The UP clinical activities are alike those in other Swiss community pharmacies, but UP mainly serves chronic ambulatory patients followed by specialists (e.g., oncology or infectious diseases), whereas other community pharmacies manage more cases of general medicine diseases in collaboration with general practitioners. The UP has a total of 54 opening hours per week. Every working day, five pharmacists (among fourteen) and six pharmacy technicians (among eighteen) ensure the clinical activities with patients. For drug validation, pharmacy technicians welcome patients and contribute to the pre-identification of DRPs and to the collection of initial information from patients and then refer to the pharmacists to support their activities (Appendix 1).

Among such activities, drug validation according to the remuneration based on a fee-for-service basis⁹ and documentation through Clin-PhADoc tool is primarily performed by two pharmacists according to a daily work shift planning. In addition, the UP operates daily an Interdisciplinary Medication Adherence Program (IMAP)¹⁷ where patients (approximately 250 patients) are seen by one of the five pharmacists, hence this activity is not considered in the present study. The characteristics of the UP have not changed throughout the duration of the study. Over this period, 16 pharmacists integrated the UP and 15 left the UP.

2.3. Data collection

Patients' fluctuation and activities in the UP depends on the

following variables: seasons, school holidays, fluctuation of the number of patients (according to specific days of activities at the UP) and medical rotation (not only from general practitioners but from specialists changing setting to gain knowledge in other medical specialty) at Unisanté (every year on May 1st and November 1st). Thus, DRPs were documented during approximately 21 working days per year to assure a systematic sampling considering the aforementioned variables (Appendix 2). In 2016, a double number of days were selected for piloting the electronic tool. In 2020, the documentation in the UP had to be reorganized due to the COVID-19 semi-containment.¹⁵

Documentation of DRPs detected was made using Microsoft Access® v2016 document based on the ClinPhADoc tool. Each year one pharmacist was responsible for managing the documentation process and supporting involved pharmacist to ensure a systematic data collection. During the days selected for documentation, two out of the five pharmacists working on drug validation evaluated their respective prescriptions and documented DRPs. Documentation included: identification of the prescription, identification of the DRP, medication involved (brand name, active substance, Anatomical Therapeutic Chemical or ATC denomination), DRP type (clinical, technical, procedural), its clinical consequence (increased toxicity, loss of efficacy), pharmacist's intervention (prescription modified or not), implied partner in DRP management (patient/caregiver, prescriber, none) and pharmacists' time to identify and manage DRPs. According to the Swiss payment scheme for pharmacist's services, one patient could present more than one prescription and one prescription could contain one or more medications and one or more DRPs (time was considered separately for each DRP, because DRP type and implied partner when managing them could differ in the same prescription).

Total number of prescriptions each day was extracted from the pharmacy software (GoldenGate® v925.5.0).

2.4. Statistical analyses

A descriptive analysis was carried out evaluating frequencies, percentages and measures of central tendency. Afterwards, Pearson's chisquare test was used to determine associations among pharmacists' working time for DRPs management and other variables (type of DRP, implied partner, working years). Pearson's chi-square test was used when dividing the pharmacists' working time as categories (0–5min; 6–15min; 16–30min; >30min) and analysis of variance (ANOVA) were used when evaluated as continuous variable (mean). In addition, inferential analysis was made to evaluate the influence of the rotation of new assistant medical practitioners to compare the beginning (May and November) and end of the rotation period (April and October) on the number and type of DRP. P-value of <0.05 indicated statistically significance. Analyses were performed using R Statistics® v4.0.5.

3. Results

From 2016 to 2021, a total number of 171 437 prescriptions were received at the UP. 14 651 prescriptions (8.5%) were received during the days selected for documentation, of which 6 844 (46.7%) were validated and documented by two of the five pharmacists. A total number of 1 550 DRPs were identified, therefore 22.6% of documented prescriptions presented DRPs (Table 1).

Regarding the ATC classification, 73 different groups were involved in DRPs. Three main groups accounted for the 23.9% of DRPs: analgesics (N02) were the most prevalent (10.7% of DRPs) followed by systemic antivirals (J05, 7.7% of DRPs) and psycholeptics (N05, 5.5% of DRPs).

The most frequent DRP was of procedural type e.g. pharmacist prescription renewal (n = 506, 32.6%). Followed by clinical DRPs: dosage/ posology (n = 263, 17.0%) and drug-drug interaction (n = 153, 9.9%). Overall mean time for the management of DRPs was 6.89 min (SD = 6.74), the longest time was for clinical DRPs: no indication (mean = 15.8 min, SD = 3.8) and side effect (mean = 12.6 min, SD = 12.9)

Table 1

Total number of validated prescriptions, prescriptions considered for documentation and DRPs.

	-					
YEAR	PRESCRIPTIONS VALIDATED PER YEAR	PRESCRIPTIONS VALIDATED DURING THE DOCUMENTATION DAYS N (%) ^a	PRESCRIPTIONS VALIDATED AND DOCUMENTED DURING THE DOCUMENTATION DAYS N (%) ⁵	DRPS DETECTED AND DOCUMENTED N (%) ^c	DRPS DOCUMENTED PER DAY MEAN (SD)	TIME FOR THE MANAGEMENT OF THE DOCUMENTED DRPS (MIN.) MEAN (SD)
2016	32 200	5 068 (15.7) ^d	1 691 (33.4)	239 (14.1)	5.6 (4.9)	7.7 (6.1)
2017	28 248	2 091 (7.4)	1 248 (59.7)	300 (24.0)	13.4 (9.0)	5.6 (5.5)
2018	29 081	2 101 (7.2)	1 014 (48.3)	237 (23.4)	10.8 (6.0)	7.1 (7.4)
2019	30 012	2 021 (6.7)	1 014 (50.2)	281 (27.7)	11.7 (7.0)	8.4 (9.4)
2020	25 793 ^e	1 553 (6.0)	849 (54.7)	224 (26.4)	10.7 (5.6)	6.0 (5.0)
2021	26 103	1 817 (7.0)	1 028 (56.6)	269 (26.2)	11.3 (6.8)	6.6 (5.3)
Total	171 437	14 651 (8.5)	6 844 (46.7)	1 550 (22.6)	9.9 (6.9)	6.9 (6.7)

^a Percentages are calculated considering the total number of prescriptions per year.

^b Percentages are calculated considering the total number of prescriptions validated.

^c Percentages are calculated considering the total number of prescriptions validated and documented.

^d Double number of days were selected for piloting the electronic tool in this first year.

^e Number of validated prescription s dropped due to COVID-19 semi-containment in Switzerland.¹⁵

Table 2

Mean time required for DRP management from 2016 to 2021 according to their type.

ClinPhADoc	DRP category and type ¹⁴	n (%)	Time dedicated to the management Mean (SD) (min.)
Procedural	Pharmacist prescription renewal	506 (32.6)	5.3 (4.6)
Clinical	Dosage/posology	263 (17.0)	7.3 (6.5)
	Drug-drug interaction	153 (9.9)	8.8 (9.4)
	Adherence, abuse, misuse	79 (5.1)	8.9 (6.4)
	Untreated problem	33 (2.1)	10.1 (8.8)
	Inadequate drug form	31 (2.0)	5.2 (3.8)
	Duration	22 (1.4)	7.1 (5.1)
	Contraindication	21 (1.4)	10.2 (8.0)
	Duplication	18 (1.2)	8.3 (5.9)
	Side effect	9 (0.6)	12.6 (12.9)
	Problem related to treatment effects	7 (0.5)	7.0 (2.2)
	No indication	6 (0.4)	15.8 (3.8)
Technical	Formal or regulatory reason	104 (6.7)	5.1 (4.2)
	Refund problem	89 (5.7)	6.5 (7.0)
	Problem of procurement	89 (5.7)	6.5 (5.0)
	Discordance with other medical data	81 (5.2)	10.7 (11.9)
	Inadequate quantity	17 (1.1)	4.8 (2.5)
	Unreadable prescription	16 (1.0)	5.7 (4.2)
	Problem related to treatment administration	4 (0.3)	6.8 (2.4)
	Problem of cost	2 (0.1)	3.5 (2.1)
TOTAL		1 550 (100.0)	6.9 (6.7)

Table 3

Prevalence of DRP from 2016 to 2021 as determined by management time dedicated by the pharmacist.

(Table 2). The majority of DRPs (n = 1 008, 65.0%) were managed in less than 5 min (Table 3). The difference in the time for DRP management was statistically significant depending on DRP type and the implied partner (p < 0.001) (Table 3).

Most DRPs (n = 726, 44.6%) were managed by the pharmacist alone. Mean time for DRP management by the pharmacist alone was lower (4.84min., SD = 4.17) than when implying the patient/caregiver (5.87min., SD = 5.76) or when the prescriber was also involved (10.73min., SD = 8.67) with statistically significant differences (p < 0.001, ANOVA test).

For most clinical and technical DRPs, pharmacists modified the prescription (n = 537, 49.2%), they also refer the patient in 6.8% cases (n = 74).

Subanalysis of the days when the rotation of assistant medical practitioners had place, showed that clinical DRPs were the most frequent DRPs (42.5%) instead of procedural. Statistically significant differences (p < 0.05) were found when the total number of observed DRPs (regardless the type) was compared. No differences were found between the beginning and end of the rotation period when stratified by the type of DRP (p = 0.20, Chi square test) (Fig. 1).

4. Discussion

The present study describes for almost six years the consistent and systematic documentation of DRPs detected and the related activities to manage them in a community pharmacy. The most frequent DRP was of procedural type and the primary action taken was management by the pharmacist alone.

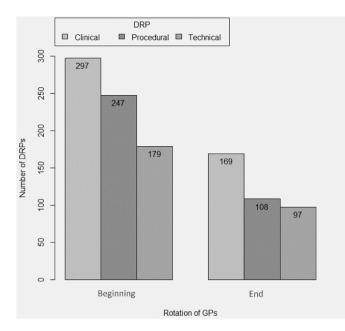
Although different pharmacists were involved in the documentation, the DRPs detected and the time required for management were similar along the years (some differences were found in 2016 when piloting). Nearly a quarter of the prescriptions validated and documented included DRPs. This result was higher than found by Nicolas et al.¹⁸ where it

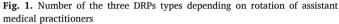
ClinPhADoc category		Time dedicated to the management, n (%) ^a				p-value
		01–05 min.	06–15 min.	16-30 min.	>30 min.	
DRP type	Clinical	343 (22.1)	250 (16.1)	43 (2.8)	6 (0.4)	
	Procedural	388 (25.0)	103 (6.6)	14 (0.9)	1 (0.1)	$< 0.001^{b}$
	Technical	277 (17.9)	101 (6.5)	15 (1.0)	9 (0.6)	
Implied partner ^c	Patient/Caregiver	280 (18.1)	86 (5.6)	10 (0.6)	2 (0.1)	<0.001 ^b
	Prescriber	173 (11.2)	242 (15.6)	50 (3.2)	13 (0.8)	
	Pharmacist alone	555 (35.8)	126 (8.1)	12 (0.8)	1 (0.1)	

^a Percentages are calculated considering the total number of DRPs (n = 1'550).

^b Pearson's Chi-squared test.

^c Several partners may be selected.





Inferential statistics were used to evaluate the influence of the rotation of assistant medical practitioners at Unisanté to compare the beginning (May and November) and end of the rotation period (April and October) on the number and type of DRP.

P-value of <0.05 indicated statistically significance.

represented 11.2%, however they only considered clinical DRPs. Other studies have found higher number of DRPs^{19–21} with lack of adherence being one of the most frequent DRP. Pharmacists in the <u>UP</u> participates in the IMAP, consequently, they proactively support patients' adherence. This probably explains why in our results, adherence was not the most common clinical DRP since lack of adherence is systematically prevented in the usual clinical approach (see Appendix 1). IMAP is not commonly introduced in community pharmacies in Switzerland: about 30 pharmacies (among 1'800) offer the same program throughout Switzerland. Likewise, in relation to the medications most frequently related to DRP, results could differ from other pharmacies due to most prescriptions in the UP being issued by specialists from the university hospital.

Medical rotation, for general practitioners and between different settings for different specialists, influenced the prevalence of DRPs, as significantly higher numbers were found at the beginning of the rotation. Therefore, documentation could be used to elaborate interprofessional coordinated interventions and training to ultimately optimize patient safety. While medical rotation has not been studied in relation to DRPs, studies have shown^{22,23} that training and evaluation programs improve the ability to prescribe.

Documentation is known to be a challenge in community pharmacies particularly due to lack of time.^{5,24} In order to develop effective clinical and administrative initiatives, documentation should meet established criteria for legibility, clarity, and completeness.^{5,11,25} The ease of completion of ClinPhADoc tool enabled the systematic documentation to compare pharmacists' workload related to DRPs¹⁴ and showed consistency among over the years. Its use should be further evaluated in other community pharmacies.

The remuneration system in Switzerland already comprises the eventual DRPs detection and management of drug validation. Pharmacists' remuneration for validating each drug is CHF4.30, regardless if a DRP is present and the stakeholders involved.⁹ Pharmacists labor cost is estimated in CHF87/hour²⁶ or CHF1.45/minute, which translates in remunerating 2.96 min for drug validation. Results found a mean time of 6.9 min to manage a DRP, which is close to results observed in another study carried out in Switzerland²⁷ that found out that drug validation was completed in 5.4 min in the absence of DRPs and 6.8 min when a DRP was present (time was determined based on observation by a pharmacy student). The time required to detect and manage DRPs in Germany was 4 min.¹⁸ In addition, clinical DRPs required more working time to be managed due to the involvement of other stakeholders. Therefore, DRPs detection and management seem not completely remunerated.

International payment programs for pharmacy services have often offered flat fees per service.²⁸ It has also been suggested that remuneration should be based on the intensity of pharmaceutical interventions.²⁹ The use of documentation systems such as ClinPhADoc has improved understanding of the frequency and nature of clinical interventions performed by pharmacists. Studies like this have already contributed in Australia⁵ for documentation to gain nationwide acceptance and eventually develop better remuneration systems. The next revision of the Swiss remuneration system will consider different situations to remunerate pharmacists (e.g., newly added medication). In addition, further studies are necessary to evaluate the global time needed for activities to better adapt the remuneration to services to avoid insufficient revenues as suggested by Houle et al. in a review carried out in 2019.³⁰

5. Strengths and limitations

To our knowledge, this is the first study conducted in community pharmacy that has documented the prevalence and management of DRPs during almost six years. The tool facilitated a systematic documentation without increasing pharmacists' workload. Since the study was conducted in a single pharmacy, external validity is limited. Further studies in several pharmacies would be necessary to expand knowledge of DRPs identification and management (including management time and implied partners). As this study only measured pharmacists' time, future research needs to consider pharmacy technicians' time who are also involved in the process.

6. Conclusions

The systematic documentation of DRPs and their management showed that a documentation process based on ClinPhADoc allowed consistent results over the years (e.g., prevalence of DRP and time needed for their management). Documentation serves for the identification of patterns of DRPs that could be eventually used to elaborate professional coordinated interventions to prevent them with the ultimate aim of increasing patient safety.

Funding statement

The present work did not receive external funding for the study.

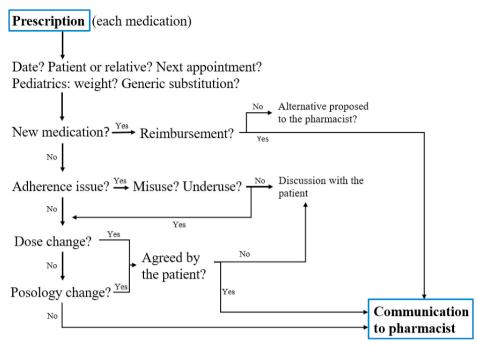
Declaration of competing interest

The authors have declared that no competing interests exist.

Acknowledgements

We thank all community pharmacists who participated in the study for their time and commitment throughout the years.

Appendix 1. Pharmacy technicians' aid in pre-identifying drug related problems



Appendix 2. Days for DRP documentation

Documentation was made three to four days (Monday, Wednesday, Friday and some weeks Saturday) for six weeks (weeks 3, 17, 25, 30, 41 and 49) each year.

	2016 ^a (since April)	2017	2018	2019	2020 ^b	2021
Week 1	April (4, 6,8,11,13,15, 19,20,25, 27, 29)	January (23, 25, 27)	January (29, 31) February (2)	January (14, 16, 18)	January (20, 22, 24)	January (18, 20, 22)
Week 2	May (2, 4, 9 11, 18, 20, 27, 30)	March (2) April (10, 12, 21)	April (9, 11, 13)	April (15, 17, 18)	Not performed	April (12, 14, 16)
Week 3	June (3, 6, 10, 13, 17, 21, 24)	May (22, 24, 26, 27)	May (14, 16, 18, 19)	May (6, 8, 10)	June (8, 10, 12, 13)	June (7, 9, 11)
Week 4	July (1, 4, 8, 11, 19, 26) August (22, 24, 26, 27)	July (31) August (2, 4, 5)	August (6, 8, 10, 11)	August (5, 7, 9)	August (3, 5, 7)	August (2, 4, 6, 7)
Week 5	October (24, 26, 28, 29)	November (6, 8, 10)	October (29, 31) November (2)	October (28, 30) November (1)	October (26, 28) November (13)	October (11, 13, 15)
Week 6	December (5, 7, 9, 10)	December (18, 20, 22)	December (18, 19, 21, 22)	December (16, 18, 20)	December (7, 9, 11, 12)	December (6, 8, 10, 11)

^a In 2016, a double number of days were selected for piloting the electronic tool.

^b In 2020, the documentation in the UP had to be reorganized due to the COVID-19 semi-containment (Bourdin A, Dotta-Celio J, Niquille A, Berger J. Response to the first wave of the COVID-19 pandemic in the community pharmacy of a University Center for Primary Care and Public Health. Res Social Adm Pharm. 2022; 18(4):2706-10.).

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N. Amador-Fernández et al.

Research in Social and Administrative Pharmacy 19 (2023) 1480-1485

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